IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	**Confirmation No.:** 3377
Robert Rioux, et al.	**Group Art Unit:** 3736
Serial No.: 10/766,608	**Examiner:** Apanius, Michael
Filed: January 27, 2004	
For: **SYSTEMS AND METHODS FOR TREATING BREAST TISSUE**	

APPEAL BRIEF-CFR 41.37

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Commissioner for Patents
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This Appeal Brief is being filed in furtherance of the Notice of Appeal, filed January 5, 2007. It contains the following items in the order indicated below as required by C.F.R. §41.37:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
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V. Summary of Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
VII. Arguments
VIII. Appendix of Claims Involved in the Appeal
IX. Evidence Appendix
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I. Real Party in Interest

The real party in interest in this appeal is Scimed Life Systems, Inc., a corporation organized under the laws of Minnesota.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes claims 1-80. Of the pending claims, claims 3, 5, 6, 10, 12-14, 17, 18, and 21-67 have been withdrawn from consideration, and claims 1, 2, 4, 7-9, 11, 15, 16, 19, 20, and 68-80 stand rejected, leaving no claims allowed. The claims on appeal are claims 1, 2, 4, 7-9, 11, 15, 16, 19, 20, and 68-80.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Claimed Subject Matter

Although the invention should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of several embodiments in order to aid in understanding the invention.

Independent claim 1 is directed to a system 100/600 for treating breast tissue (see page 7, lines 14-15; page 14, lines 5-8; page 17, lines 3-6; page 21, lines 5-9; Figs. 1, 3C, 4A-4B, and 6). The system 100/400/600 comprises a cannula 102/300/402/602 having at least one fluid conveying lumen 108/308/408/608-612 (see page 7, lines 16-18; page 11, lines 4-7; page 14, lines 15-18; page 16, line 17 to page

17, line 2; page 17, lines 6-8, page 21, lines 9-12; Figs. 1, 3C, 4A-4B, and 6). The cannula 102/300/402/602 is configured for insertion into a breast duct such that the at least one lumen 108/308 is in fluid communication with the breast duct (see page 11, lines 9-20; page 18, lines 1-2, 13-15; page 21, lines 14-17). The system 100 further comprises a tissue diagnostic device 130 slidably disposable within the at least one lumen 108/308 (see page 7, lines 14-15; page 10, lines 7-9; page 21, lines 12-13; Figs. 1 and 6). The system 100 further comprises a tissue treatment device 330 slidably disposable within the at least one lumen 108/308/408/608 (see page 15, lines 20-22; page 16, lines 5-7; page 17, lines 10-12; page 18, lines 3-5; page 22, lines 1-2; Fig. 3C).

Independent claim 15 is directed to a system 600 for treating breast tissue (see page 21, lines 5-9; Fig. 6). The system 600 comprises a cannula 602 having a fluid conveying lumen 610 (see page 21, lines 8-11; Fig. 6). The cannula 602 is configured for insertion into a breast duct such that the lumen 610 is in fluid communication with the breast duct (see page 21, lines 14-16; page 21, line 21 to page 22, line 2). The system 600 further comprises a tissue imaging device 620 slidably disposable within the lumen 610 (page 21, lines 13-14; Fig. 6). The system 600 further comprises a tissue treatment device 630 secured to, or slidably disposed within the lumen 610 of, the cannula 602 (page 21, line 21 to page 22, line 2; Fig. 6).

Independent claim 71 is directed to a system 100/600 for treating breast tissue (see page 7, lines 14-15; page 14, lines 5-8; page 17, lines 3-6; page 21, lines 5-9; Figs. 1, 3C, 4A-4B, and 6). The system 100/400/600 comprises a cannula 102/300/402/602 having a fluid conveying lumen 108/308/408/608 (see page 7, lines 16-18; page 11, lines 4-7; page 14, lines 15-18; page 16, line 17 to page 17, line 2;

page 17, lines 6-8, page 21, lines 9-12; Figs. 1, 3C, 4A-4B, and 6). The cannula 102/300/402/602 is configured for insertion into a breast duct such that the lumen 108/308 is in fluid communication with the breast duct (see page 11, lines 9-20; page 18, lines 1-2, 13-15; page 21, lines 14-17). The system 100 further comprises a tissue diagnostic device 130 slidably disposable within the lumen 108/308 (see page 7, lines 14-15; page 10, lines 7-9; page 21, lines 12-13; Figs. 1 and 6). The system 100 further comprises a tissue treatment device 330 slidably disposable within the lumen 108/308/408/608 (see page 15, lines 20-22; page 16, lines 5-7; page 17, lines 10-12; page 18, lines 3-5; page 22, lines 1-2; Fig. 3C).

VI. Grounds of Rejection to be Reviewed on Appeal

A) Whether claims 1, 7-9, 11, 15, 19, 20, 68-71, and 76-80 are unpatentable under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,840,909 ("Gatto").

B) Whether claims 2, 72, and 75 are unpatentable under 35 U.S.C. §103(a) as being obvious over Gatto in view of U.S. Patent No. 5,949,929 ("Hamm").

C) Whether claims 4, 16, 73, and 74 are unpatentable under 35 U.S.C. §103(a) as being obvious over Gatto in view of U.S. Patent No. 6,497,706 ("Burbank").

VII. Arguments

A. Rejection under 35 U.S.C. 102(b) over Gatto

Applicant respectfully submits that the Examiner erred in rejecting claims 1, 7-9, 11, 15, 19, 20, 68-71, and 76-80 under 35 U.S.C. §102(b) as being anticipated by Gatto. Notably, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. (See MPEP §2131; Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2

USPQ2d 1051, 1053 (Fed. Cir. 1987)). As discussed below, Gatto does not disclose each and every element required by claims 1, 7-9, 11, 15, 19, 20, 68-71, and 76-80.

The pertinent claim language at issue is "slidably disposable within the at least one [fluid carrying] lumen" (claims 1 and 15) and "slidably disposable within the [fluid carrying] lumen" (claim 71). In concluding that the endoscopy assembly of Gatto includes a fluid carrying lumen in which a tissue diagnostic device and tissue treatment device are slidably disposable, the Examiner contends that the imaging device 12 disposed in the lumen 37 (see Fig. 5) and the laser fiber 50 disposed in the lumen 49 (see Fig. 6) are slidably disposed in the fluid conveying lumen 33 because the lumens 37, 49 are disposed in the lumen 33 (see paragraph bridging pages 6-7 of Office Action, dated October 13, 2006). Applicant disagrees that the lumens 37, 49 are disposed in the fluid conveying lumen 33, as required by claims 1, 15, and 71.

Notably, claims must be interpreted as broadly as their terms reasonably allow, which means that the words of the claim must be given their plain meaning unless otherwise defined in the written description (see MPEP §2111.01(I); In re Zletz, 893 F.2d 319, 321 (Fed. Cir. 1989)). In determining the plain meaning of a claim term, resort can be made to dictionary definitions (see MPEP §2111.01(II)). The dictionary definition of the term "lumen" is "a bore of a tube (as of a hollow needle or catheter) (see Merriam Webster's Collegiate Dictionary).

In determining the plain meaning of a claim term, resort can also be made to the written description of the application (see MPEP §2111.01(II)). While the MPEP is somewhat vague as to the role that the written description has in construing claim terms, the MPEP is clear that, at the least, the written description can be used to determine whether the dictionary meaning of a term is consistent with any definition

given to the term in the written description. In the present case, while the written description does not provide an explicit definition for the term "lumen," the manner in which the written description describes lumens and their relation to devices that are disposed in the lumens is consistent with the dictionary meaning of the term "lumen" provided above. There is nothing in the written description that indicates that a "lumen" is anything other than a "bore of a tube," and in the case of the claims, a bore of a cannula. Thus, a "lumen" is not the tangible portion of a tube, but rather a bore or cylindrical space within the tube.

Gatto discloses two embodiments: (1) a cannula 30 having a fluid conveying lumen 33 and a lumen 37 in which an endoscope 12 is disposed (Fig. 5); and (2) a cannula 30 having two fluid conveying lumens 52, 54, a lumen 47 in which an endoscope 12 is disposed, and a lumen 49 in which a laser fiber 50 is disposed (Fig. 6). While the cannula 30 is formed by mounting a tube 36 to the inner wall of the tube 32, the resulting lumens 33, 37 formed by this arrangement are separate and distinct from each other. Likewise, while the cannula 40 is formed by mounting tubes 46, 48 to the inner wall of the tube 42, the resulting lumens 47, 49, 52, 54 are separate and distinct from each other.

Although the Examiner has concluded that the lumens 37, 49 are found within the larger fluid conveying lumen 33, and thus further concluded that the endoscope 12 and laser fiber 50 are slidably disposed in the fluid conveying lumen 33 (see paragraph bridging pages 6-7 of Final Office Action, dated October 13, 2006), the only logical way in which a lumen can be disposed within another lumen is if they are in a concentric relationship; that is, one lumen is completely surrounded by the other lumen. Otherwise, the respective lumens will be in a side-by-side arrangement, in which case,

the lumens cannot be considered to be disposed in one another. As clearly shown in Figs. 5 and 6 of Gatto, the lumen 37 is in a side-by-side relationship with the fluid conveying lumen 33, and the lumen 49 is in a side-by-side relationship with the fluid conveying lumens 52, 54.

For example, as shown in Fig. 5, the lumen 37 (i.e., the circular space within the cylindrical tube 36) in which the imaging device 12 is disposed is completely separate from the fluid conveying lumen 33 (i.e., the crescent-shaped space within sheath 32); that is, the lumen 37 is above the lumen 33—not contained within it. Thus, the imaging device 12 is not slidably disposed within—but rather slidably disposed above—the fluid conveying lumen 33. As shown in Fig. 6, the lumen 49 in which the laser fiber 50 disposed is completely separate from the fluid conveying lumens 52, 54 (i.e., the two side-by-side half crescent-shaped spaces within sheath 42); that is, the lumen 49 is between the lumens 52, 54. Thus, the laser fiber 50 is not slidably disposed within—but rather slidably disposed between—the fluid conveying lumens 52, 54.

Notably, the lumens illustrated in Figs. 5 and 6 are clearly in a side-by-side relationship that is no different from an extruded cannula construction through which side-by-side lumens have been formed, and in fact, the cannula 40 illustrated in Fig. 6 appears to have been formed as a single extrusion. Certainly, in the cases where lumens are formed using a single extrusion, a device that is disposed is one of the lumens cannot be reasonably construed as being disposed in another of the lumens, and there is no reason why one would differently conclude in the case where a tube is mounted to the inner surface of another tube, since the resulting cannula constructions are the same, i.e., a cannula having side-by-side lumens through which different devices or fluid can be respectively disposed, which is in contrast to the claimed

invention where a lumen is used to both convey fluid and house a diagnostic device, imaging device, and/or tissue treatment device.

As such, Appellant submits that independent claims 1, 15, and 71, as well as the claims depending therefrom (claims 7-9, 11, 19, 20, 68-70, and 76-80), are not anticipated by Gatto.

B. Rejection under 35 U.S.C. 103(a) over Gatto and Hamm

Appellant respectfully submits that the Examiner erred in rejecting claims 2, 72, and 75 under 35 U.S.C. §103(a) as being obvious over Gatto in view of Hamm. To establish obviousness, it must be found that the differences between the claimed invention and the prior art would have been obvious to a person having ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). Applicants believe that the differences between claims 2, 72, and 75 and the teachings of Gatto and Hamm would not have been obvious to a person having ordinary skill in the art. In particular, as discussed above, Gatto does not disclose a cannula that has a fluid conveying lumen in which a diagnostic device, imaging device, or a tissue treatment device is slidably disposed, and Hamm does not supplement this failed teaching.

As such, Appellant submits that claims 2, 72, and 75 are not obvious over the combination of Gatto and Hamm.

C. Rejection under 35 U.S.C. 103(a) over Gatto and Burbank

Appellant respectfully submits that the Examiner erred in rejecting claims 4, 16, 73, and 74 under 35 U.S.C. §103(a) as being obvious over Gatto in view of Burbank. Again, to establish obviousness, it must be found that the differences between the claimed invention and the prior art would have been obvious to a person having

ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). Applicants believe that the differences between claims 4, 16, 73, and 74 and the teachings of Gatto and Burbank would not have been obvious to a person having ordinary skill in the art. In particular, as discussed above, Gatto does not disclose a cannula that has a fluid conveying lumen in which a diagnostic device, imaging device, or a tissue treatment device is slidably disposed, and Burbank does not supplement this failed teaching.

In addition, claims 4, 16, 73, and 74 require the ablation electrode to be included as part of the tissue treatment device. In contrast, the electrodes 12, 13 disclosed in Burbank is used to cut and capture a tissue specimen from a target tissue site in a biopsy procedure—not to treat the target tissue site. Thus, even if the electrode arrangement disclosed in Burbank could somehow be incorporated into the cannula disclosed in Gatto, the resulting structure would still not include every element required by claims 4, 16, 73, and 74.

Notably, it is an established principle that if a proposed modification would render the prior art device or method being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (See M.P.E.P. §2143.01). See In re Gordon, 733 F.2d 900 (Fed. Cir. 1984). The Examiner has essentially attempted to incorporate the features of a biopsy probe that takes whole tissue samples into a probe that takes cytological samples. In particular, the Examiner has not set forth how the biopsy electrodes 12, 13 disclosed in Burbank, which are intended to cut whole tissue samples, could be incorporated into the cannula assembly disclosed in Gatto without defeating its purpose of a taking a cytological sample. Simply put, the Examiner has not provided why one of ordinary skill in the art would be

motivated to incorporate tissue cutting electrodes into the cytological specimen probe of Gatto, and how this would be accomplished.

As such, Appellant submits that claims 4, 16, 73, and 74 are not obvious over the combination of Gatto and Burbank.

Respectfully submitted,

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VIII. Appendix of Claims Involved in the Appeal

1. A system for treating breast tissue, comprising:

a cannula having at least one fluid conveying lumen, the cannula configured for insertion into a breast duct such that the at least one lumen is in fluid communication with the breast duct;

a tissue diagnostic device slidably disposable within the at least one lumen; and

a tissue treatment device slidably disposable within the at least one lumen.

2. The system of claim 1, wherein the tissue diagnostic device comprises a spectrometer.

4. The system of claim 1, wherein the tissue treatment device comprises an ablation electrode.

7. The system of claim 1, further comprising a media delivery device coupled to the at least one lumen.

8. The system of claim 1, further comprising an aspirator coupled to the at least one lumen.

9. The system of claim 1, further comprising a tissue imaging device slidably disposable within the at least one lumen.

11. The system of claim 9, wherein the imaging device comprises an endoscope.

15. A system for treating breast tissue, comprising:

a cannula having a fluid conveying lumen, the cannula configured for insertion into a breast duct such that the lumen is in fluid communication with the breast duct;

a tissue imaging device slidably disposable within the lumen; and

a tissue treatment device secured to, or slidably disposed within the lumen of, the cannula.

16. The system of claim 15, wherein the tissue treatment device comprises an ablation electrode.

19. The system of claim 15, further comprising a media delivery device coupled to the lumen.

20. The system of claim 15, further comprising an aspirator coupled to the lumen.

68. The system of claim 1, wherein the tissue diagnostic device and the tissue treatment device are slidably disposable within the same one of the at least one lumen.

69. The system of claim 1, wherein the at least one lumen comprises two lumens.

70. The system of claim 15, wherein the tissue treatment device is slidably disposable within the lumen.

71. A system for treating breast tissue, comprising:

a cannula having a fluid conveying lumen, the cannula configured for insertion into a breast duct such that the lumen is in fluid communication with the breast duct;

a tissue diagnostic device slidably disposable within the lumen; and

a tissue treatment device slidably disposable within the lumen.

72. The system of claim 71, wherein the tissue diagnostic device comprises a spectrometer.

73. The system of claim 71, further comprising a first electrode secured to distal

end of the cannula, wherein the tissue treatment device comprises a second electrode in a bipolar arrangement with the first electrode.

74. The system of claim 71, wherein the tissue treatment device comprises an ablation electrode.

75. The system of claim 71, wherein the tissue treatment device comprises an optical fiber for delivering laser energy.

76. The system of claim 71, further comprising a media delivery device coupled to the lumen.

77. The system of claim 71, further comprising an aspirator coupled to the lumen.

78. The system of claim 71, further comprising a tissue imaging device slidably disposable within the lumen.

79. The system of claim 78, wherein the imaging device comprises a CCD camera.

80. The system of claim 78, wherein the imaging device comprises an endoscope.

IX. Evidence Appendix

A. U.S. Patent No. 6,840,909. Originally cited by the Examiner in the Office Action, dated May 8, 2006.

B. U.S. Patent No. 5,949,929. Originally cited by the Examiner in the Office Action, dated May 8, 2006.

C. U.S. Patent No. 6,497,706. Originally cited by the Examiner in the Office Action, dated May 8, 2006.

X. Related Proceedings Appendix

None.

US006840909B2

(12) **United States Patent**
Gatto

(10) **Patent No.: US 6,840,909 B2**
(45) **Date of Patent: Jan. 11, 2005**

(54) **APPARATUS AND METHOD FOR INTRADUCTAL CYTOLOGY**

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(73) Assignee: **Acueity, Inc.**, Palo Alto, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 292 days.

(21) Appl. No.: **10/104,016**

(22) Filed: **Mar. 25, 2002**

(65) **Prior Publication Data**

US 2003/0181823 A1 Sep. 25, 2003

(51) **Int. Cl.**[7] **A61B 10/00**

(52) **U.S. Cl.** **600/562**; 600/563; 600/570; 600/128; 600/156; 604/27

(58) **Field of Search** 600/562–566, 600/570, 571, 573, 108, 114, 128, 130, 153, 156, 158, 159, 182; 604/19, 27, 35

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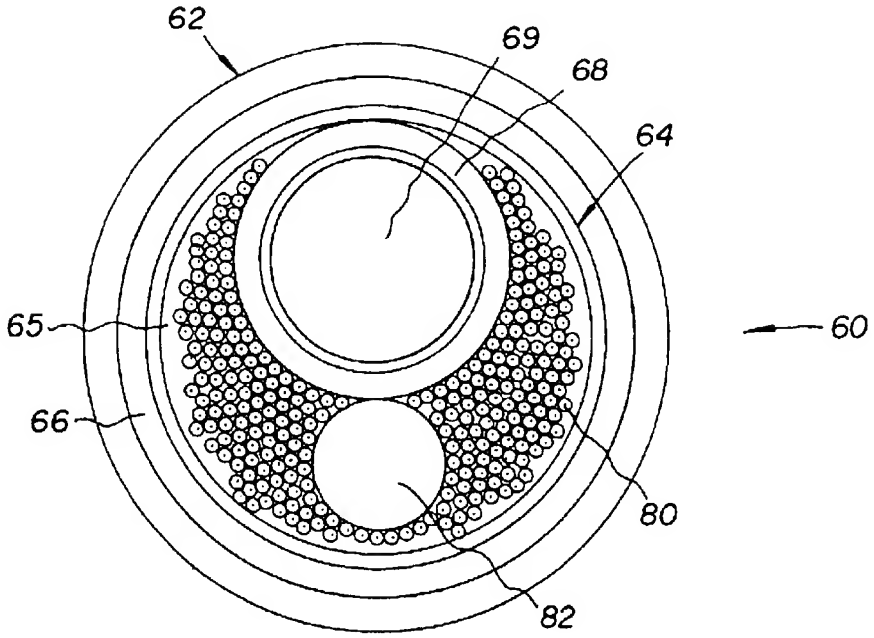
Primary Examiner—Charles Marmor
(74) *Attorney, Agent, or Firm*—Olson & Hierl, Ltd.

(57) **ABSTRACT**

The invention is directed toward a micro-endoscope assembly for the removal of tissue and cells from breast ducts comprising a cylindrical guide tube with a beveled distal end defining an internal cylindrical passageway and a first smaller cylindrical tube eccentrically formed in the cylindrical passageway of a smaller diameter than the tube internal cylindrical passageway and adapted to receive and guide an endoscope with a handle assembly wherein the smaller cylindrical tube together with an inner wall surface of the cylindrical guide tube forms a second passageway. A second conduit of a smaller diameter than the smaller cylindrical tube is mounted in the second passageway to divide the second passageway into two separate divided sections and is of sufficient diameter to receive a laser fiber and a micro-endoscope is mounted in the smaller cylindrical tube and a laser is mounted in the second cylindrical tube in the second passageway. The assembly is inserted into a mammary duct and the interior of the duct is viewed until an abnormality is determined in the duct. The tissue and cells from the abnormality area are dislodged, irrigated and aspirated through a suction channel to a removable collection device.

7 Claims, 3 Drawing Sheets



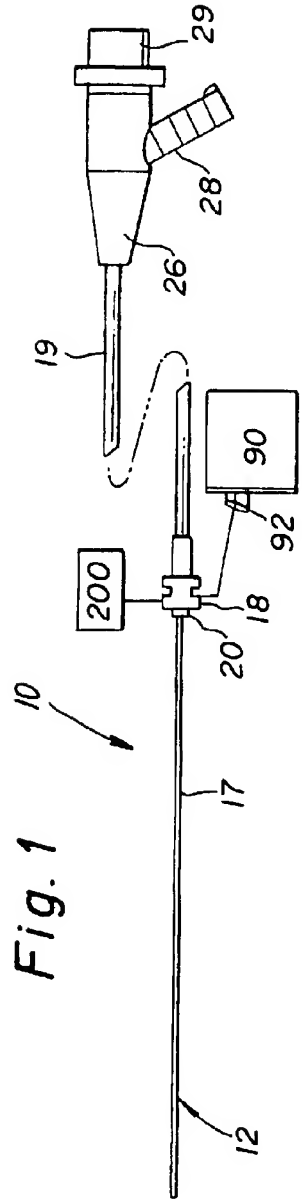


Fig. 1

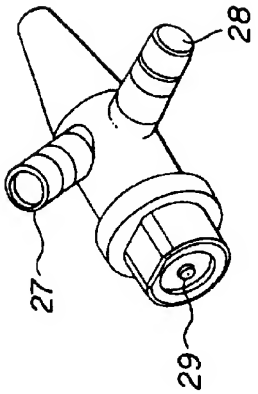


Fig. 3

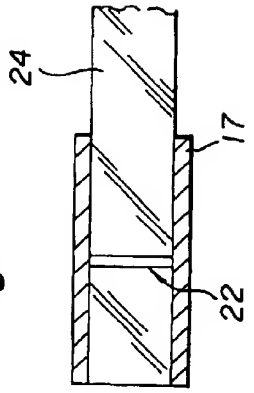


Fig. 2

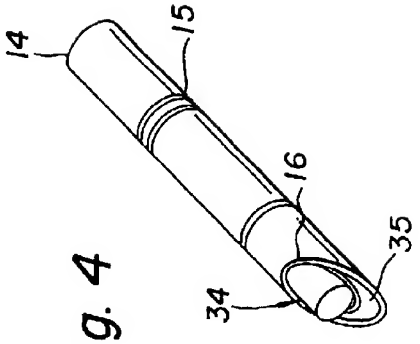


Fig. 4

Fig. 5

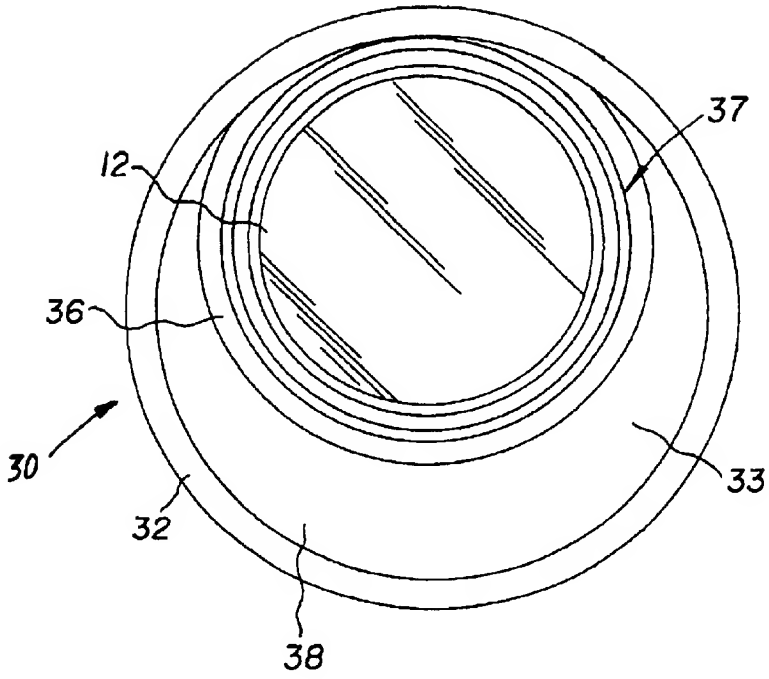


Fig. 6

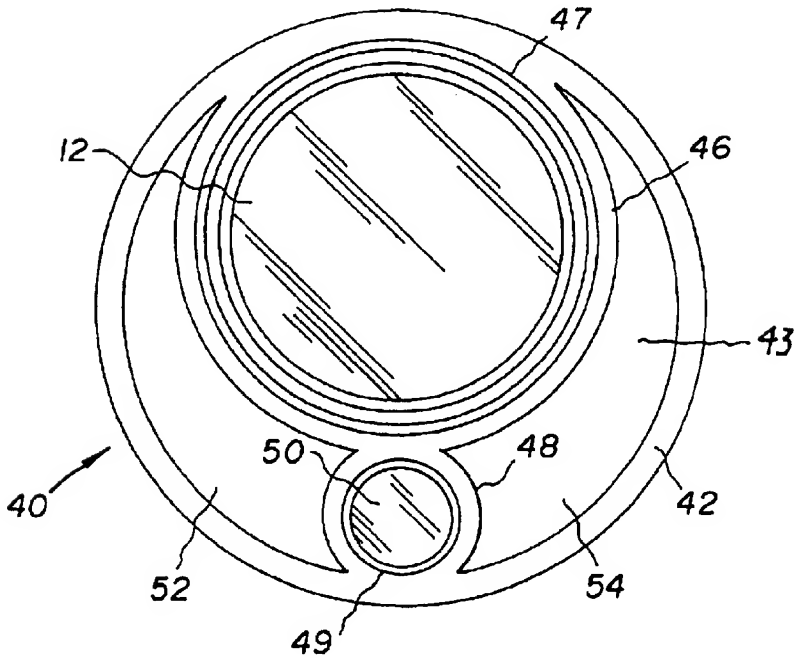
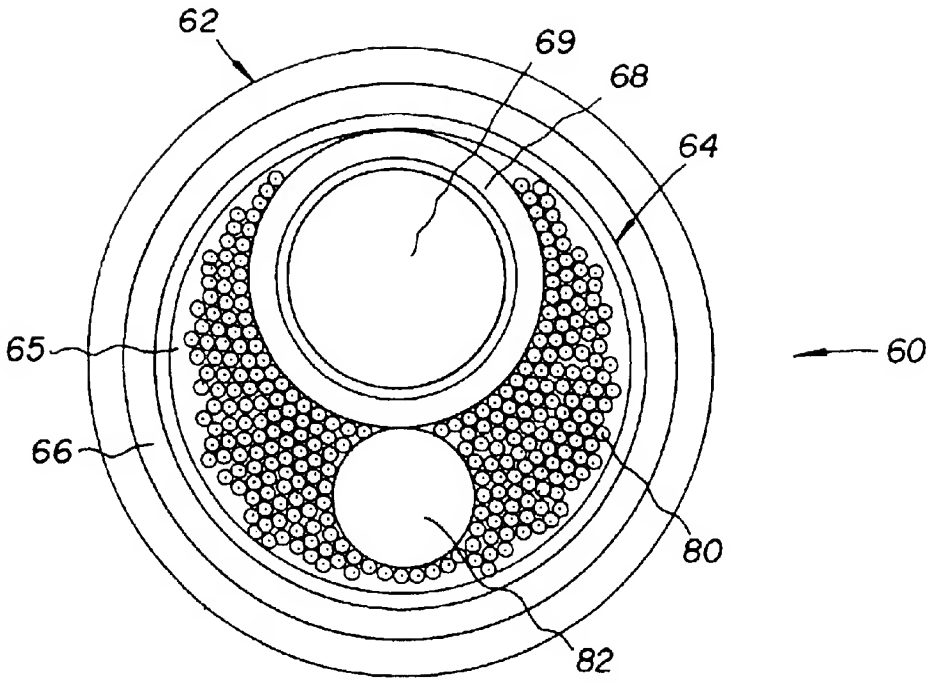


Fig. 7



APPARATUS AND METHOD FOR INTRADUCTAL CYTOLOGY

RELATED APPLICATION

There are no related applications.

FIELD OF INVENTION

The present invention is generally directed toward the detection of breast cancer and more specifically toward the detection and collection of cancer and/or abnormal growth tissue and cells in the mammary breast ducts of women.

BACKGROUND OF THE INVENTION

A leading disease incurred by women is breast cancer. Breast cancer is the second leading cause of death for women of all ages and the leading cause of death for women aged 25–55.Approximately one in eight women will incur breast cancer in their lifetimes. The current medical standard for determining breast cancer in women is mammography. However mammography fails to detect up to 20% of breast cancers in women over 50 and up to 40% of breast cancers in younger women. Breast cancer grows slowly but under current techniques such as mammography the average detection is only on cancer growths which have been growing over seven years at which time the growth size of the cancer generally ranges between 1 and 2 cm. Almost 90% of all breast cancer originates in the mammary ducts, where it grows slowly in its initial stages.

After detection breast cancer is generally treatable in three ways: surgery, radiation and chemotherapy. Surgery and radiation, of course, have risks and disadvantages well known to those of skill in the art. Chemotherapy also can be particularly disadvantageous as, for example, when the drugs involved cause sickness to the patient when they enter the blood stream.

Endoscopic biopsy procedures are typically performed with an endoscope and an endoscopic biopsy forceps device (bioptome). The endoscope is a long flexible tube carrying fiber optics and having a narrow lumen through which the bioptome is inserted. The bioptome generally includes a long flexible coil having a pair of opposed jaws at the distal end and manual actuation means at the proximal end which opens and closes the jaws. During a biopsy tissue sampling operation, the surgeon guides the endoscope to the biopsy site while viewing the biopsy site through the fiber optics of the endoscope. The bioptome is inserted through the narrow lumen of the endoscope until the opposed jaws arrive at the biopsy site. While viewing the biopsy site through the fiber optics of the endoscope, the surgeon positions the jaws around a tissue to be sampled and manipulates the actuation means so that the jaws close around the tissue. A sample of the tissue is then cut and/or torn away from the biopsy site while it is trapped between the jaws of the bioptome. Keeping the jaws closed, the surgeon withdraws the bioptome from the endoscope and then opens the jaws to collect the biopsy tissue sample.

A biopsy tissue sampling procedure often requires the taking of several tissue samples either from the same or from different biopsy sites. Unfortunately, most bioptomes are limited to large areas of entry and to taking a single tissue sample, after which the device must be withdrawn from the endoscope and the tissue collected before the device can be used again to take a second tissue sample.

Attempts have been made to provide an instrument which will allow the taking of tissue samples within small duct areas. A simple double barrel catheter with adjacent lumens is disclosed in U.S. Pat. No. 6,221,622 with one of the lumens being used to irrigate the milk duct of a breast and the other lumen being used to aspirate the fluid which has entered the duct allowing a continuous flow of saline through the duct which hopefully carries enough cells and tissues for a biopsy. Problems in the use of such an instrument include the small size required by the narrow small diameter lumens which can be blocked or limit the flow of fluid back through the aspiration lumen and thus preclude significant tissue collection or cause duct collapse. While the '622 Patent shows a small lumen size the size problem is magnified with the other existing prior art if the same were to be applied to breast ducts and the endoscope is to be used with mammary duct inspection because of the small size and thin cell walls of the mammary ducts.

Thus almost all known multiple sample biopsy instruments are precluded from use with an endoscope because of their size and rigidity. These include the "punch and suction type" instruments disclosed in U.S. Pat. No. 3,989,033 and U.S. Pat. No. 4,522,206. Both of these devices have a hollow tube with a punch at the distal end and a vacuum source coupled to the proximal end. A tissue sample is cut with the punch and suctioned away from the biopsy site through the hollow tube. It is generally recognized, however, that dry suctioning tissue samples (i.e., without the use of an irrigating fluid) through a long narrow flexible bioptome is exceptionally difficult.

The present device provides multiple sampling ability to an instrument which must traverse the narrow lumen of an endoscope or cannula housing an endoscope which in turn must traverse the small diameter of a breast duct. Numerous examples of prior art exist which are able to operate in a larger area such as U.S. Pat. No. 4,651,753 which discloses a rigid cylindrical member attached to the distal end of a first flexible tube. The cylindrical member has a lateral opening and a concentric cylindrical knife blade is slidably mounted within the cylindrical member. A second flexible tube, concentric to the first tube is coupled to the knife blade for moving the knife blade relative to the lateral opening in the cylindrical member. A third flexible tube having a plunger tip is mounted within the second flexible tube and a vacuum source (a syringe) is coupled to the proximal end of the third tube. A tissue sample is taken by bringing the lateral opening of the cylindrical member upon the biopsy site, applying vacuum with the syringe to draw tissue into the lateral opening, and pushing the second flexible tube forward to move the knife blade across the lateral opening. A tissue sample is thereby cut and trapped inside the cylindrical knife within the cylindrical member. The third flexible tube is then pushed forward moving its plunger end against the tissue sample and pushing it forward into a cylindrical storage space at the distal end of the cylindrical member. Approximately six samples can be stored in the cylindrical member, after which the instrument is withdrawn from the endoscope. A distal plug on the cylindrical member is removed and the six samples are collected by pushing the third tube so that its plunger end ejects the samples.

It can thus be seen that the preferred mode of operation of virtually all existing endoscopic tools currently being used is that a gripping action at the distal end of the instrument is effected by a similar action at the proximal end of the instrument. Another endoscopic multiple sample biopsy device is disclosed in U.S. Pat. No. 5,171,255 which discloses a flexible endoscopic instrument with a knife-sharp cutting cylinder at its distal end. A coaxial anvil is coupled to a pull wire and is actuated in the same manner as

conventional biopsy forceps. When the anvil is drawn into the cylinder, tissue located between the anvil and the cylinder is cut and pushed into a storage space within the cylinder. Several samples may be taken and held in the storage space before the device is withdrawn from the endoscope. Traditional biopsy forceps provide jaws which can grasp tissue frontally or laterally. Even as such, it is difficult to position the jaws about the tissue to be sampled. Lateral sampling is even more difficult.

A traditional form of biopsy is disclosed in U.S. Pat. No. 5,542,432 which shows an endoscopic multiple sample biopsy forceps having a jaw assembly which includes a pair of opposed toothed jaw cups each of which is coupled by a resilient arm to a base member. The base member of the jaw assembly is mounted inside a cylinder and axial movement of one of the jaw assembly and cylinder relative to the other draws the arms of the jaws into the cylinder or moves the cylinder over the arms of the jaws to bring the jaw cups together in a biting action. The arms of the jaws effectively form a storage chamber which extends proximally from the lower jaw cup and prevents accumulated biopsy samples from being squeezed laterally out from between the jaws during repeated opening and closing of the jaws and the lower jaw cup enhances movement of the biopsy samples into the storage chamber. The device can hold up to four samples before it must be retrieved out of the endoscope. However, in some biopsy procedures it is sometimes desirous to retrieve more. In addition, it has been found that samples within the chamber can stick together and make determinations of which sample came from which biopsy site somewhat difficult.

U.S. Pat. No. 5,538,008 discloses a multiple sample bioptome which purports to take several samples and transfers each sample by water pressure through a duct to the proximal end of the instrument, where each sample can be individually retrieved. The device includes a plastic jaw set biased in an open position and coupled to the distal end of an elongate tube, up to seven feet long. The tube defines a duct. A sleeve extends over the tube and a water flow passage is provided between the tube and the sleeve. An aperture is provided in the tube to permit the water flow passage to meet the duct at the distal end of the tube. Withdrawing the tube into the sleeve is disclosed to force the jaws closed and enable a sample to be cut from tissue and lodge in the duct. The water flow passage is disclosed to enable water to flow under pressure from the proximal end of passage to the distal end of the passage, through the aperture and into the distal end of the duct and to be aspirated to the proximal end of the duct, thereby transferring with it any sample contained in the duct to the proximal end where the sample can be retrieved.

Generally in the field of surgery, mechanical cutters utilizing a reciprocal or rotating cutting element have been used to sever tissue of a patient. Cutting devices that use light energy to cut tissue are also well known in the art. Electro surgical devices for tissue excision or cauterization similarly have a long medical history. Such instruments have encountered numerous problems due to their one dimensional capabilities and have failed to meet many of the needs of a surgeon performing a surgical procedure.

While some lasers are effective coagulators and cutters, certain other types of lasers, CO_2 lasers for example, are effective at cutting tissue but are not good coagulators. Certain lasers are good coagulators but are poor tissue cutters. The YAG laser, for example, is sometimes used as a coagulator but is not considered to be a good tissue cutter.

The ablation of tissue in various other regions of the body has been previously studied. U.S. Pat. No. 5,107,513 describes the general use of three types of lasers. Carbon dioxide (CO_2) laser radiation is intensely absorbed by water and thus acts as a surgical knife and vaporizer, its penetration depth in tissue being 0.03 mm. Argon lasers are minimally absorbed by water but intensely absorbed by hemoglobin and penetrate 1 to 2 mm in most tissue. These lasers are especially useful in coagulating bleeding points in small superficial vessels. Neodymium-Yttrium-Aluminum-Gamet (Nd:YAG) lasers are poorly absorbed by both water and hemoglobin. These lasers are able to penetrate large volumes of tissue, blood clots and coagulate large bleeding vessels. A Holmium laser with a 2100 nm wavelength has good cutting capabilities and its coagulating properties are similar to those of the Nd:YAG laser, penetrating to about 0.4 mm for most tissue. The Holmium laser was noted to be useful for the following applications: (1) in the gastrointestinal tract for bleeding ulcers, excision of lesions, recanalization of obstruction and arresting of massive bleeding; (2) in general surgery for cutting without bleeding; (3) in urology for treatment of the bladder; (4) for creation of vascular anastomoses; (5) for aneurysms, patent ducts, varicose veins and hemangiomas to generate thrombosis; (6) for dissolution of gall bladder stones by insertion of a fiber optic into the bile duct; (7) for destruction of tumors in the bronchial tree; (8) in gynecology for fallopian tube shrinkage and removal of polyps, benign tumors and septum and for ablation of the endometrium for menorrhagia; (9) in cardiac surgery for treatment of obstructed valves; and (10) in neurosurgery for removal of solid as well as vascular tumors.

U.S. Pat. No. 5,147,354 describes the use of a mid-infrared laser endoscope for performing arthroscopy. Holmium:YAG and Holmium:YLF lasers with wavelengths in the 1800 to 2200 nm range are used for producing laser ablations in a fluid field. The radiation is said to be easily transmitted through a conventional quartz optical fiber.

Thus, there is a need in the art for new and better micro-cannula/endoscope assemblies and methods for using same that can be used to directly visualize the mammary ducts of a breast where visualization is by means of endoscopic devices, direct visualization (as opposed to creation of photographic images) and offers the additional advantage that the equipment required is comparatively simple to use and is less expensive than the equipment required to create photographic displays from such images. In addition, there is a need in the art for a method of identifying diseased or abnormal tissue during surgical procedures so that immediate resection or biopsy of the identified tissue can be performed without the necessitating the use of additional instrumentation.

SUMMARY OF THE INVENTION

The present invention is directed toward the detection, sample collection and/or treatment of abnormal growths and cancer located in the mammary ducts of women's breasts which in the present invention is when the cancer is typically between two and three years old with a size of about 0.2 mm. This is over 50 times more sensitive than a standard mammogram. According to a further aspect of the invention, a method is provided for retrieving one or more biopsy tissue sample(s) using a micro-endoscope assembly having irrigation and aspiration capabilities. The micro-endoscope assembly includes a proximal actuation handle, an elongate flexible member extending from the proximal actuation handle and having an irrigation conduit, a distal assembly located at the distal end of the biopsy instrument, and a fluid pressure device in fluid connection with the irrigation conduit.

The method comprises the steps of: inserting the distal end of the micro-endoscope assembly into a lactiferous duct of the breast of a woman patient; viewing the inside of the duct as the distal end of the endoscope travels along the duct until a tissue abnormality is viewed; positioning the distal assembly proximate to a tissue to be sampled; detaching a tissue and/or cell sample from the tissue abnormality site using the beveled end of the cannula of the micro-endoscope assembly; introducing irrigation and subsequently a negative pressure through the fluid pressure device and the irrigation conduit while transporting fluid through the irrigation conduit to flush the tissue sample through an aspiration conduit from the distal end to the proximal end of the endoscope into a reservoir and member container therein and recovering the tissue sample.

It is thus an object of the invention to provide a micro-endoscope assembly which can view the interior of a lactiferous duct to ascertain abnormalities and obtain tissue and cell samples from the site.

It is an object of the invention to utilize a micro-cannula with an eccentrically mounted endoscope conduit to provide maximum room in the micro-cannula for other additional functions including aspiration, irrigation and laser treatment.

It is yet another object of the micro-endoscope assembly invention to provide for the extraction of intraductal tissue for more reliable diagnosis with more precision and less trauma than conventional biopsy procedures.

It is also an object of the micro-endoscope assembly invention to provide for micro-endoscopic screening of defined groups of patients at high risk for breast cancer.

It is an additional object of the micro-endoscope assembly invention to obtain direct real-time intraductal images allowing detection of cancerous and precancerous lesions and growths as small as 0.2 mm.

It is an still additional object of the micro-endoscope assembly invention to extract tissue and cell samples for further diagnosis.

It is also an object of the micro-endoscope assembly invention to create an endoscope assembly which can be easily handled by the physician.

These and other objects, advantages, and novel features of the present invention will become apparent when considered with the teachings contained in the detailed disclosure which along with the accompanying drawings constitute a part of this specification and illustrate embodiments of the invention which together with the description serve to explain the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded side elevational view of the endoscope used in the present invention;

FIG. **2** is an enlarged partial cross section of the lens end of the endoscope in FIG. **1**;

FIG. **3** is a perspective orientated view of the back end of the endoscope showing a light post and laser post;

FIG. **4** is a perspective view of a portion of the front end of the micro-endoscope assembly;

FIG. **5** is an enlarged elevational view of the front end of the micro-endoscope shown in FIG. **4**;

FIG. **6** is an alternate embodiment of the micro-endoscope assembly invention; and

FIG. **7** is another embodiment of a micro-endoscope.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed towards a micro-endoscope assembly **10** which can be used and inserted into the lactiferous ducts of the breast of a woman patient and a method for intraductal cytology. The lactiferous ducts generally range in number from about six to about twelve in women and lead from areas of the breast to the nipple where they are in parallel vertical orientation with each other. The ducts have a very thin cell wall ranging from 3 to 4 cells in thickness and are resilient. The ducts have a smooth inner surface and white color which resemble visually the interior of a standard PVC pipe.

The best mode and preferred embodiment of the invention is shown in FIGS. **1–5**. The micro assembly **10** consists of tube or guide cannula **14** which seats and guides the endoscope **12**. The cannula **14** has an outer cylindrical wall **16** which defines an internal passageway which runs along its length to seat and guide the endoscope **12**. Cannula tube **14** may be a rigid steel tube ranging from 5–20 cm long having an outer diameter ranging from 0.5 mm to approximately 1.2 mm or alternatively may be a semi-rigid tube made of flexible or transparent plastic, or some other suitable material, and having the same or a longer length. The exterior of the cannula is marked with marking indicia **15** as seen in FIG. **4** so that the depth of penetration of the micro-endoscope assembly into the duct can be noted. The marking indicia can be in the form of rings of opaque, translucent or light reacting material or any other suitable geometry which is easily visible to the surgeon's eye. The marking indicia can be printed onto the outer surface of the cannula or imbedded in the cannula structure material. Various cannula are envisioned to be interchangeable with the endoscope **12** by unscrewing one guide cannula from the endoscope front hub **18** and its associated connector member **20** and screwing one another onto the connector member. The hub member **18** has ports which are fluidly connected to a vacuum source **90** with a cell collection reservoir **92** containing a tissue and cell collection member (not shown), the reservoir **92** being in fluid communication with an aspiration pump **200**.

The endoscope **12** is provided with tube body **17** formed with objective lens **22** at its distal end and image guide **24** as is more clearly shown in FIG. **2**. The endoscope **12** has a proximal end in the form of a back member **26** having a light post **27**, a laser post **28** and a video port **29** as seen in FIG. **3**.

The preferred cannula embodiment **30** as shown in FIG. **5** has a cylindrical outer cannula or sheath **32** formed with a beveled distal end **34** as shown in FIG. **4** forming a shovel type nose **35**. The inner wall of sheath **32** defines a cylindrical inner channel **33** which has an inner cylindrical tube **36** eccentrically mounted thereon. The tube **36** defines the endoscope channel **37** and holds endoscope **12**. The inner cylindrical tube **36** is eccentrically mounted in cylindrical inner channel **33** to the wall of the cannula sheath **32** and its outer surface together with the inner surface of the sheath or tube **32** to define a moon shaped channel **38** which acts as a biopsy channel providing irrigation and aspiration. The irrigation/aspiration channel **38** can also be used as a port through which a laser, such as an Eximer laser, could be utilized. In that situation, the laser is inserted through the multiple purpose channel **38** until it reaches the patient's duct area containing cells and/or tissue showing abnormal characteristics.

An alternate embodiment of the cannula **40** is shown in cross section in FIG. **6**. This embodiment has a cylindrical outer cannula or sheath **42** which defines a cylindrical inner channel **43** in which an inner cylindrical tube **46** is eccentrically mounted to the wall of sheath **42**. The cylindrical tube **46** defines the endoscope channel conduit **47** to hold the

endoscope **12**. A second smaller cylindrical tube **48** is eccentrically mounted in channel **43** adjacent to and integral with a portion of the wall of tube **46** and a wall of the cannula **42** to form a laser fiber channel **49** which holds laser fiber **50**. The cylindrical tube structure **46** divides the moon shaped channel up into two separated segments **52** and **54** which serve as the irrigation and aspiration channels for the assembly or for a channel for bundled illumination fibers and/or a mechanical tissue scraping or cutting device. These segmented channels allow the physician to irrigate and aspirate the area of the duct containing abnormal cells or structure and deposit the same onto a sample tissue and cell container in the form of a foam disk or porous substrate to provide a cytology sample of the duct area for examination. The aspiration conduit is of a diameter sufficient to retrieve biopsy samples from the distal end of the instrument.

Another embodiment as shown in cross section in FIG. **7** is a micro-endoscope **60** which is constructed with an outer cannula or sheath **62** and an inner cannula or sheath **64** positioned within the chamber of cannula **62** to define an irrigation/aspiration channel **66** defined by the inner wall surface of cannula **62** and the outer wall surface of inner cannular **64**. The inner wall of cannula **64** defines a cylindrical inner chamber **65** which has an inner cylindrical tube **68** mounted therein. The tube **68** defines the image guide **69** and holds the lens. The inner cylindrical tube **68** is eccentrically mounted in cylindrical chamber **65** adjacent the inner wall of the cannula **64** and is substantially surrounded by a bundle of individual light fibers **80** and is adjacent to a laser fiber **82** which is positioned adjacent to outer wall of the inner cannula **64** within the bundle of laser fibers **82**.

FIG. **1** also shows the endoscope **12** with the lens tube **17** and tube portion **19** coupled between hub **18** and back end **26**. Tube **19** includes a passageway in it's interior capable of holding fiber optic strands and/or illumination strands. Such strands run from video port **29**, through tube portion **19** into hub **18**. The strands run through hub **18** into the inner passageway of tube portion **17** though or outside of the working channel, as described in more detail below. These strands provide both a light source to the area of the the duct in which cytology is to be taken. The back end **26** is formed with a light source post connector **27** and laser post connector **28**. The tube portion **14** which has an outer diameter of approximately 1.2 mm has a working channel, a plurality of light fibers **80** and a lens **22**. The light fibers **80** run the length of the guide tube **17** and provide light to the areas of interest. The light fibers are commercially available. The tube cannula **14** can alternately carry the light fibers or have them molded in the tube material. The lens **22** also runs longitudinally down inner passage of guide tube **17**. The laser fiber **50**, **82** transmits the laser energy out the distal end of the endoscope via the contact laser tip to the surgical site. Suitable lasers which can be used with the invention are manufactured by Surgical Laser Technology, Inc.

Because the cannula tube is of such a small outer diameter, the physician can manipulate the tube from the proximal end in order to scrape cells free of the tissue by engaging the same with the beveled end **34** and shovel tip **35**. The physician can then irrigate the location by ejecting saline water under pressure through the irrigation channel through the operation of the pump **200** which can be a syringe. This causes the saline water injected into the patient to mix with and carry the scraped biopsy cells and tissue. Such water and cells can be withdrawn by a vacumn source **90** and deposited on the tissue collection strata held in reservoir **92**. The tissue collection strata can take the form of a small disk shaped device having layered porous foam which fits in a reservoir **92** of the aspiration channel of the micro-endoscope assembly. The disk has several layers of foam having different porosity and density. One of the layers traps tissue particles and another layer traps cells. The disk can be removed after each biopsy usage and marked in a container as to the duct from which it was removed and the depth of length of duct where it came from.

The endoscope **12** is used in conjunction with a video monitor and prismatic screen (not shown). The video port **29** is coupled to a video camera which is in turn coupled to a video monitor as is well known in the art and has an attached prismatic screen manufactured by Acueity Inc. The video camera may be of many different commercially available models, although CCD cameras are particularly useful in this type of application. Specifically, a Panasonic GS99-NTSC medical video endoscopy camera, from Matsushita Electric Corporation of America, has been found to be useful. Moreover, it has been found that in such a camera ¼ inch CCD chip is more advantageous than a ½ inch CCD chip, because it provides an image with smaller pixels. Such chips are included in CCD cameras and also are commercially available from many sources such as, for example, the Sony Corporation of America. The video monitor may be any of a number of commercially available video monitors.

It is not necessary to include a prismatic screen to use the endoscope of the present invention. However, the use of such a screen is advantageous because, as described above, the screen provides an image with increased clarity and perception of depth by causing the brain of the viewer to interpret depth cues present in the image. This increased perception of depth is particularly advantageous in medical procedures like those that employ endoscopes because of the small dimensions involved and the limited lighting available in the interior of a patient's body.

In operation the micro-endoscope assembly **10** using the rigid guide tube **14** is placed in a lactiferous duct in the patients breast after the nipple has been numbed The physician can view the interior of the duct, which has a white smooth surface, as the endoscope passes on its way through the duct to the area of interest which has an abnormal appearance and is found by watching the screen attached to video monitor. Once the duct area of interest is reached, the physician can manipulate the biopsy tube end **35** to dislodge the tissue and cells in the tissue area and retrieve cells and tissue from that area by irrigating the area and aspirating the fluid and tissue/cells to a collection site where the same are deposited on an easily removable cytology disc which traps cells and tissue or are poured into a sterilized plastic container, and taken to pathology for diagnostic testing. If the lens of the endoscope **10** is needed to be cleared of blood or tissue the aspiration channel is used as an irrigation channel by applying a liquid under pressure through the use of a syringe attached to the irrigation port.

The principles, embodiments and modes of operation of the present invention have been described in the foregoing specification. The invention that is sought to be protected herein, however, is not to be considered as limited to the particular forms disclosed, since these are to be regarded as illustrative rather than restrictive. Variations and changes may be made by those skilled in the art without departing from the spirit and scope of the invention. For example, the present invention is not limited to the particular dimensions or uses described, except as explicitly defined in the claims. Instead, the embodiments described here should be regarded as illustrative rather than restrictive. Variations and changes may be made by others without departing from the scope of the present invention as defined by the following claims:

What I claim is:

1. A micro-endoscope assembly for the removal of tissue and cells from breast ducts comprising a cylindrical guide tube including an inner wall defining an internal cylindrical passageway, a smaller diameter cylindrical tube concentrically mounted in said cylindrical passageway to form a cylindrical space there between forming an irrigation/aspiration chamber, a light guide and lens tube eccentrically mounted in said smaller diameter cylindrical tube and adapted to receive therein a light guide and lens, a plurality of illumination fibers mounted in said smaller cylindrical tube engaging an outer wall of said light guide and lens tube holding the same in place within the smaller diameter cylindrical tube and a laser fiber mounted and received in said smaller diameter cylindrical tube between the outer wall of said light guide and lens tube and said inner wall of said cylindrical guide tube engaging the outer wall of said light guide and lens tube and surrounded by and engaging directly against said illumination fibers.

2. A micro-endoscope assembly as claimed in claim 1 wherein said irrigation/aspiration chamber is connected by a conduit to a tissue cell collection reservoir.

3. A micro-endoscope assembly as claimed in claim 1 wherein said cylindrical guide tube has marking indicia placed thereon to provide duct depth penetration measurements.

4. A micro-endoscope assembly as claimed in claim 3 wherein said cylindrical guide tube marking indicia is in the form of rings.

5. A micro-endoscope assembly as claimed in claim 1 wherein said cylindrical guide tube has a distal beveled end.

6. A micro-endoscope assembly as claimed in claim 1 wherein said cylindrical guide tube has a distal end which is shovel shaped.

7. A micro-endoscope assembly as claimed in claim 1 wherein said cylindrical guide tube has a distal end which is cylindrical.

* * * * *

US005949929A

United States Patent [19]

Hamm

[11] Patent Number: 5,949,929

[45] Date of Patent: Sep. 7, 1999

[54] **ROTATABLY CONNECTING OPTICAL FIBERS**

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[73] Assignee: **Boston Scientific Corporation**, Natick, Mass.

[21] Appl. No.: **09/229,371**

[22] Filed: **Jan. 13, 1999**

Related U.S. Application Data

[62] Division of application No. 08/758,146, Nov. 25, 1996, Pat. No. 5,872,879.

[51] **Int. Cl.**[6] **G02B 6/26**

[52] **U.S. Cl.** **385/25**

[58] **Field of Search** 385/24–25, 27, 385/31, 39, 53, 147

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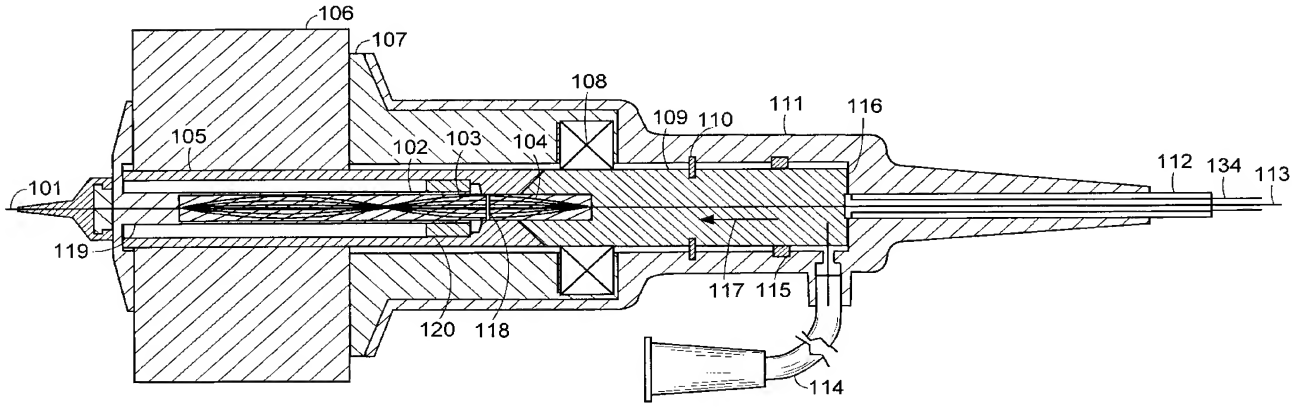
Primary Examiner—Akm E. Ullah

Attorney, Agent, or Firm—Testa, Hurwitz & Thibeault, LLP

[57] **ABSTRACT**

A connection includes an interventional medical device having a rotatable optical fiber, an assembly having a conduit for conveying a light beam to the rotatable fiber as well as a rotor and a fixed housing, and a coupling. A drive mechanism is attached to the rotor for continuously rotating the rotor. The coupling includes a rotatable portion attachable to a proximal end of the rotatable fiber and to the rotor so as to permit the rotatable fiber to rotate continuously with the rotor while the rotatable fiber remains in axial alignment with the light beam. The coupling also includes a stationary shield surrounding the rotatable portion. The stationary shield is attachable to the fixed housing so as to urge the rotatable portion and the rotor together. The proximal end of the rotatable portion of the coupling has a vee-shaped coupling surface that complements a distal end surface of the rotor. The rotor is at least partially hollow and includes a bearing that holds the light beam conduit in axial alignment with the rotatable fiber when the rotatable portion of the coupling engages the rotor. The rotatable fiber may be disengageable from the rotatable portion of the coupling when the stationary shield does not engage the fixed housing. The rotatable fiber may be surrounded by a sheath that is attachable to the stationary portion of the coupling. A fluid port connected to the stationary portion of the coupling enables introduction of fluid into the sheath and around the rotatable optical fiber.

19 Claims, 13 Drawing Sheets



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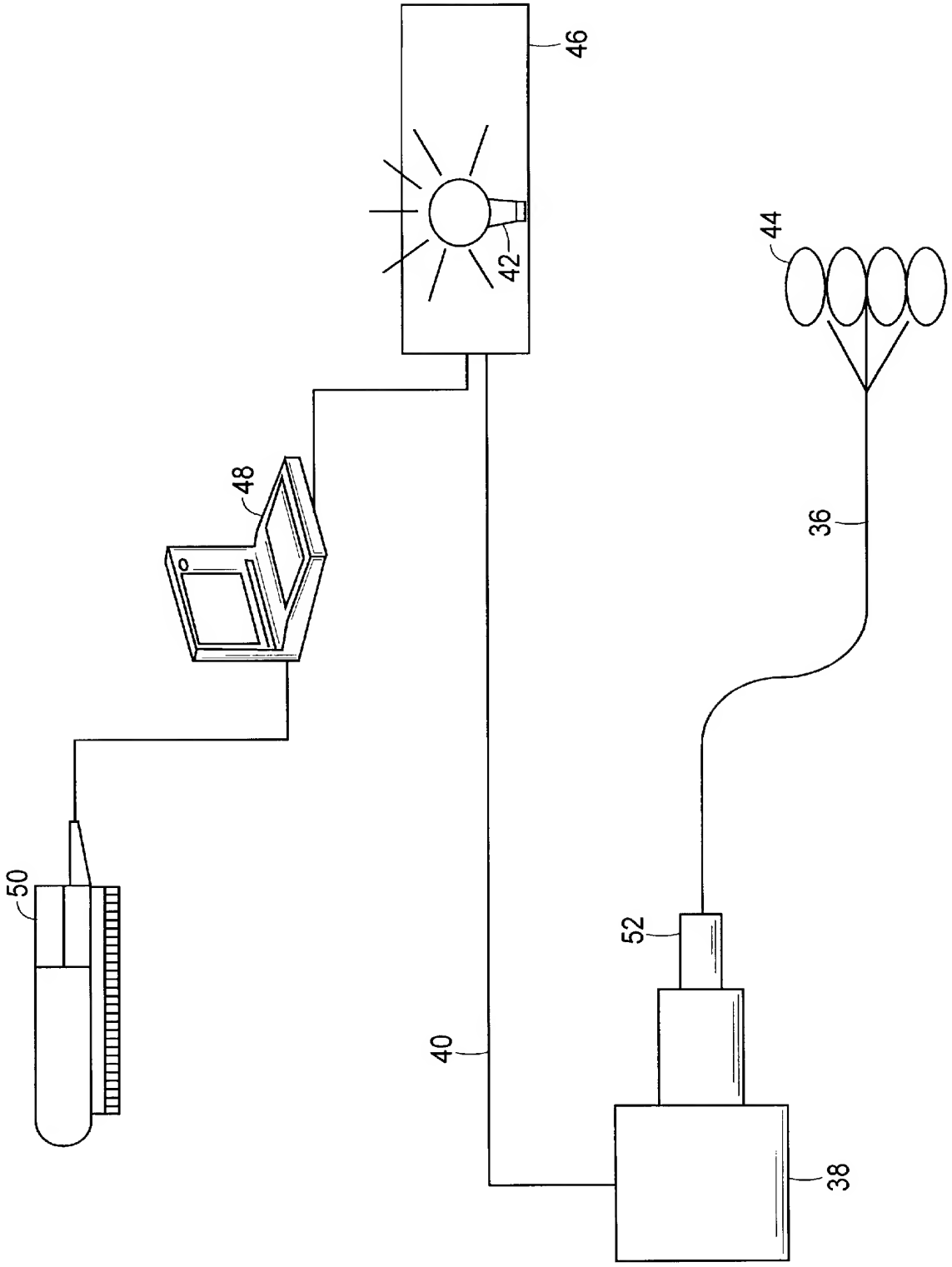

FIG. 1

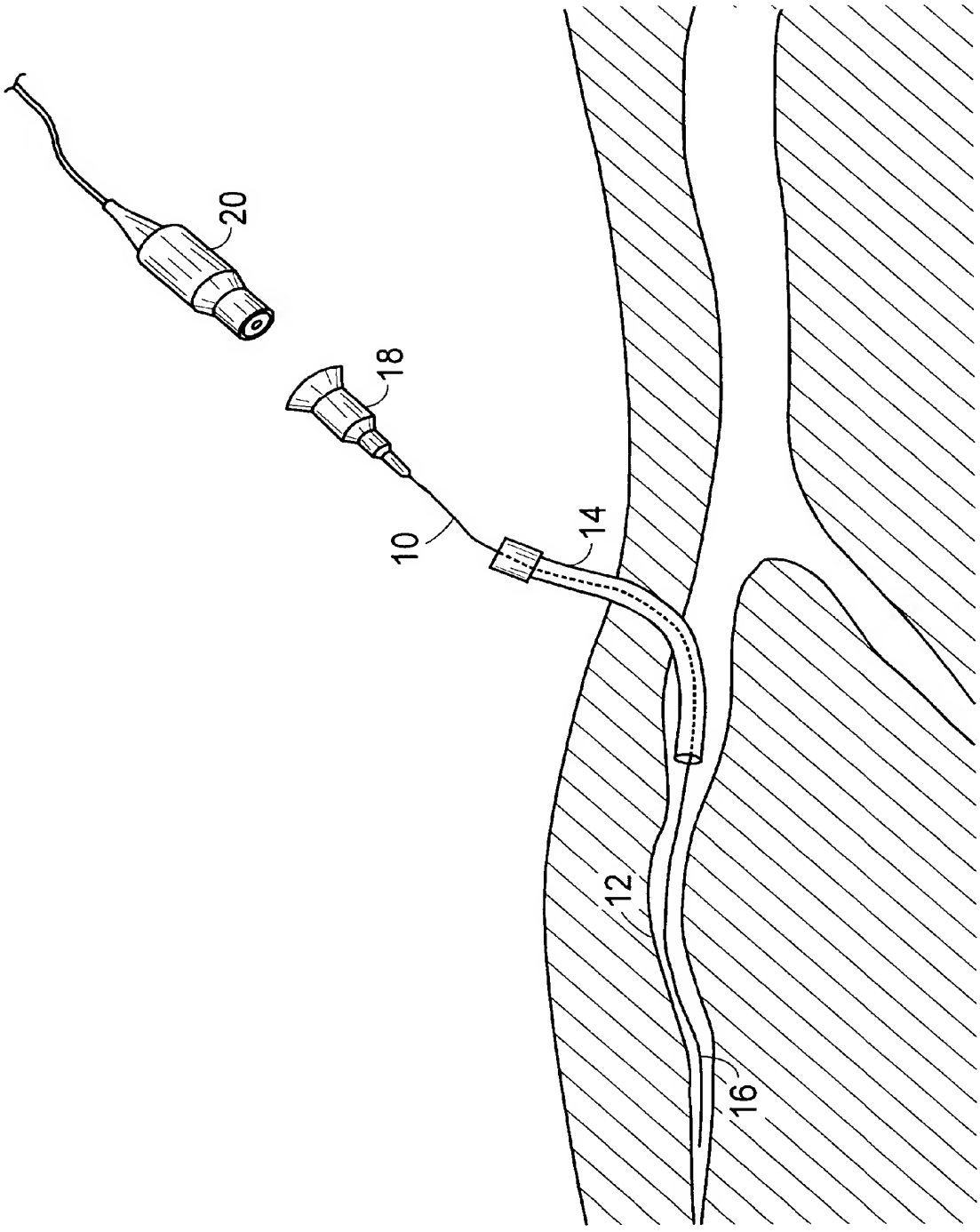

FIG. 2

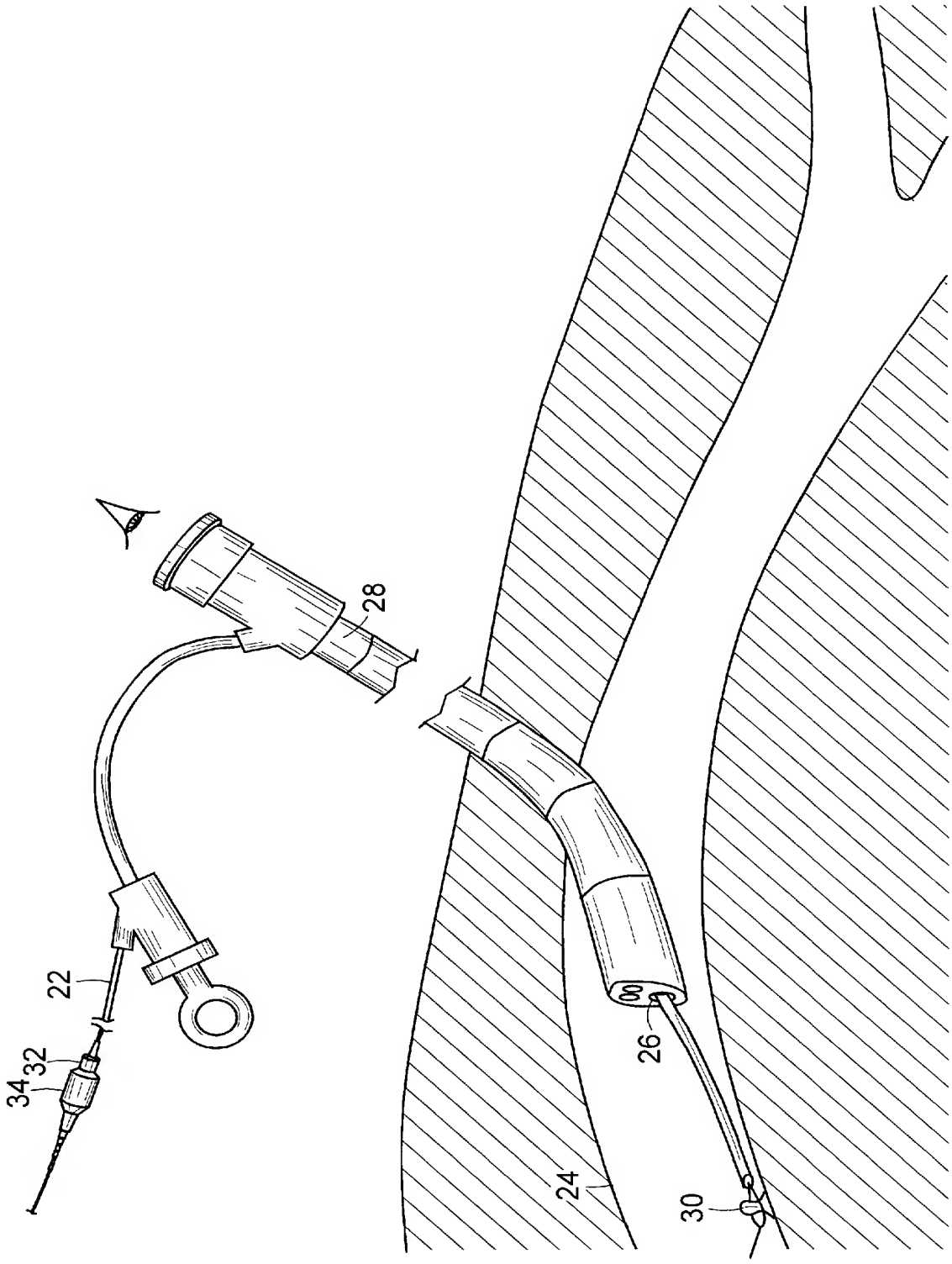

FIG. 3

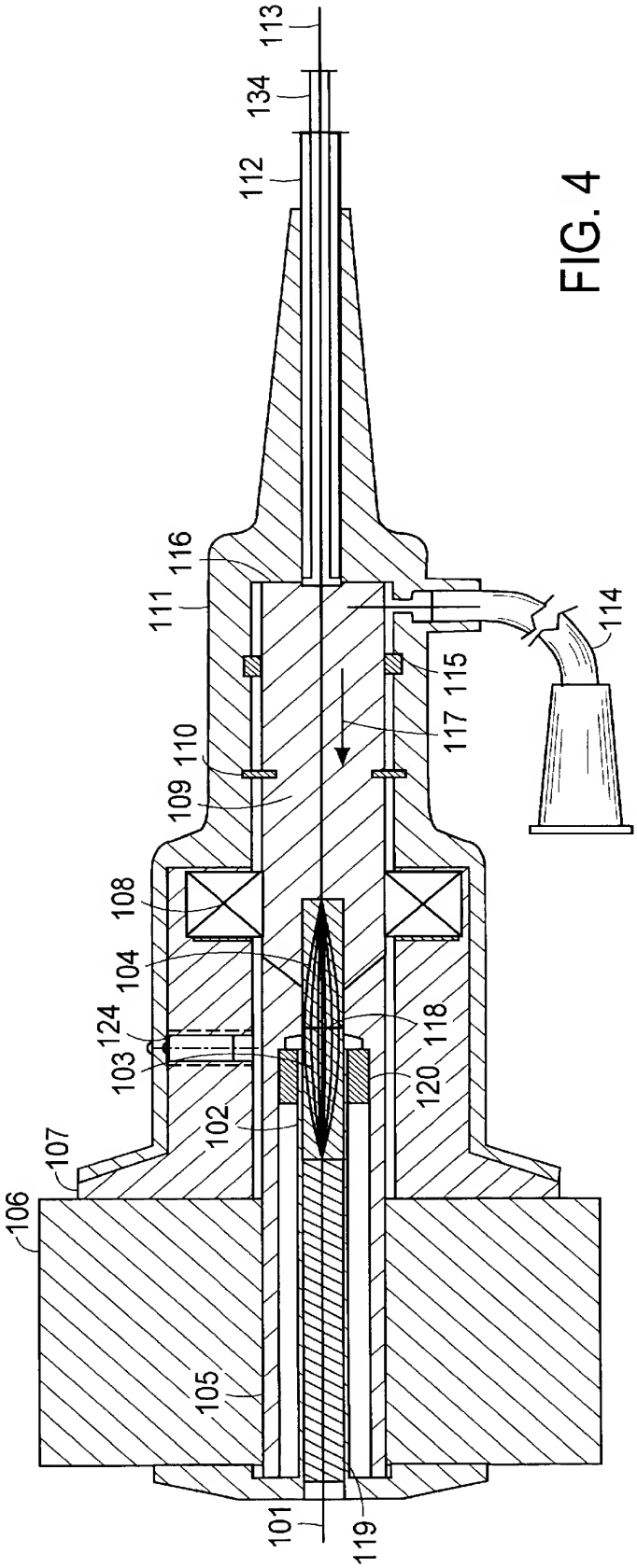
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FIG. 4

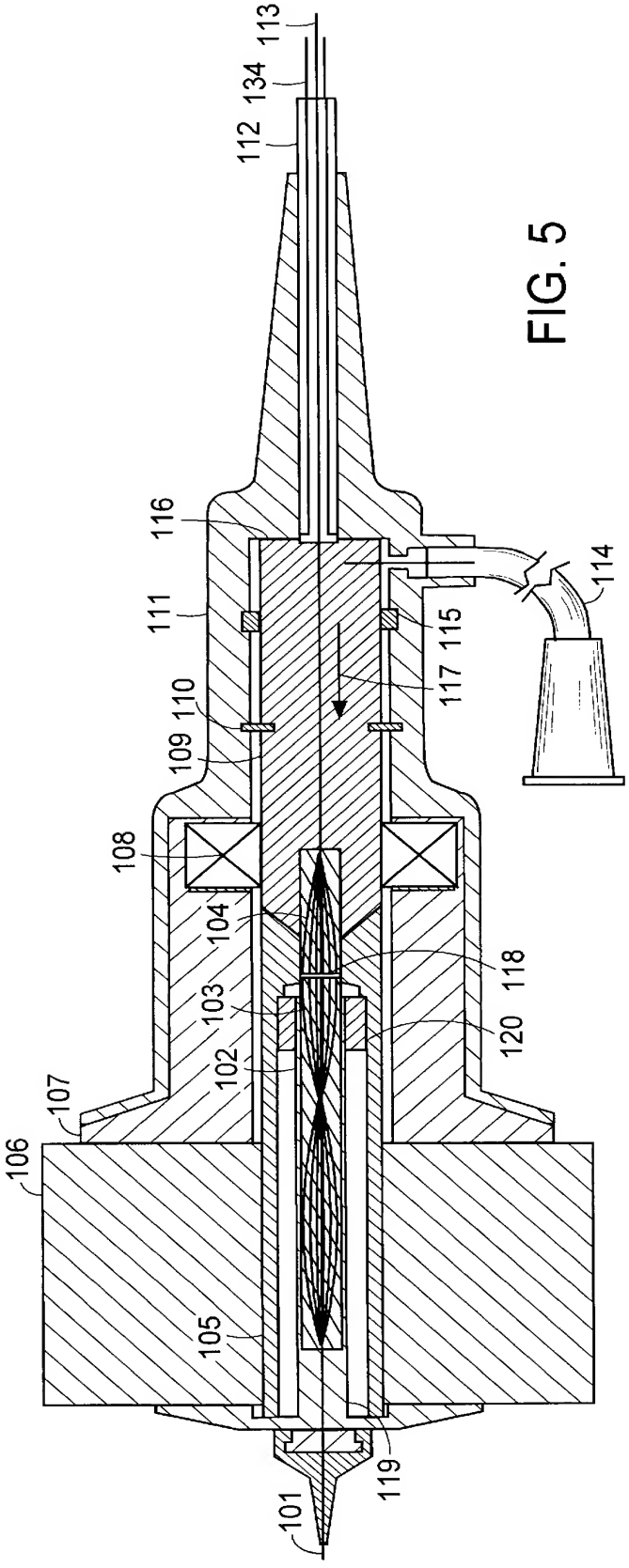

113
134
112
116
111
110
109
108
104
103
102
107
106
105
101
119
120
118
117
115
114

FIG. 5

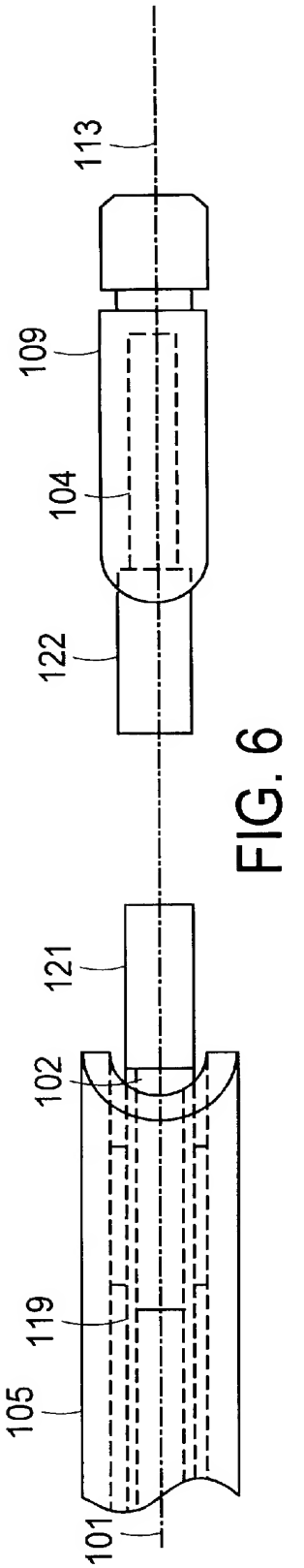


FIG. 6

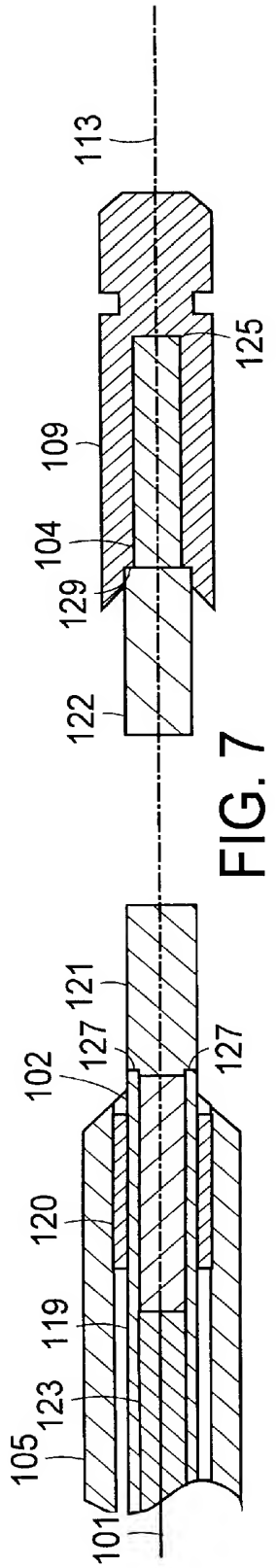


FIG. 7

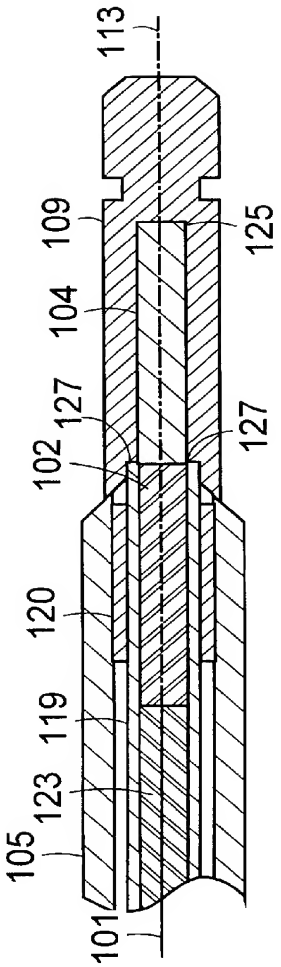


FIG. 8

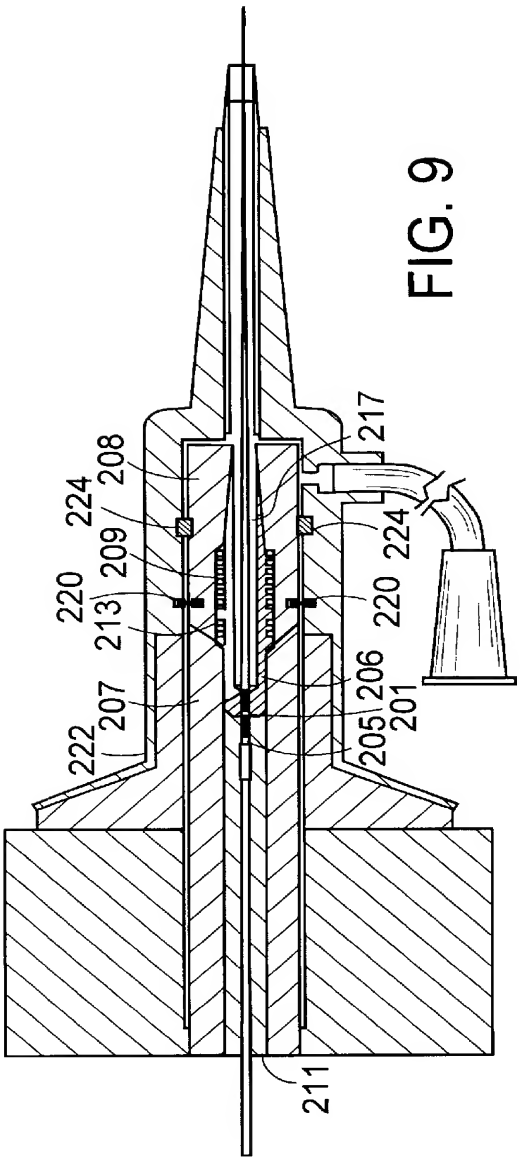

208
224
209
220
213
207
222
217
224
220
206
201
205
211

FIG. 9

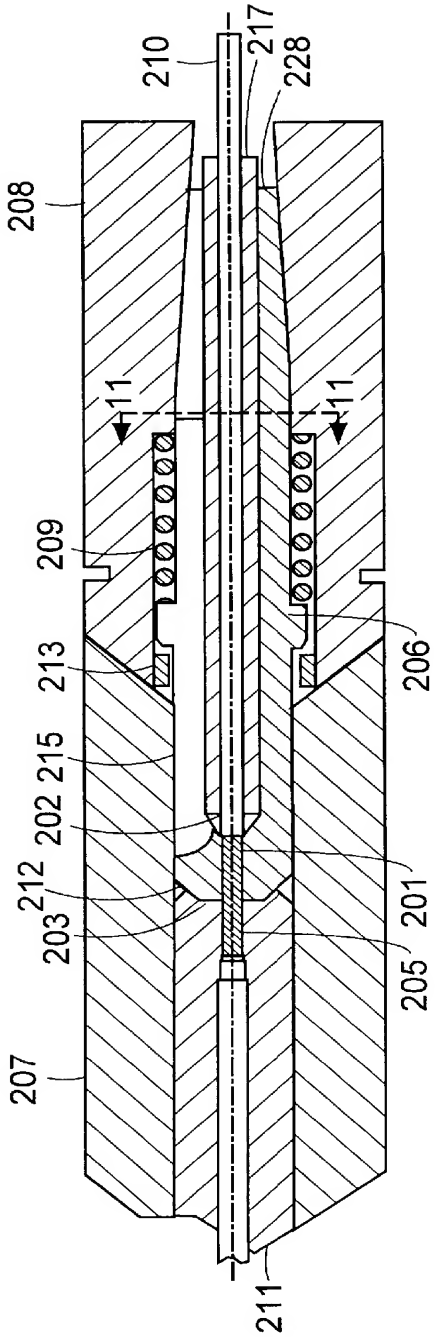

210
217
228
208
11
11
209
213
215
202
212
203
207
206
201
205
211

FIG. 10

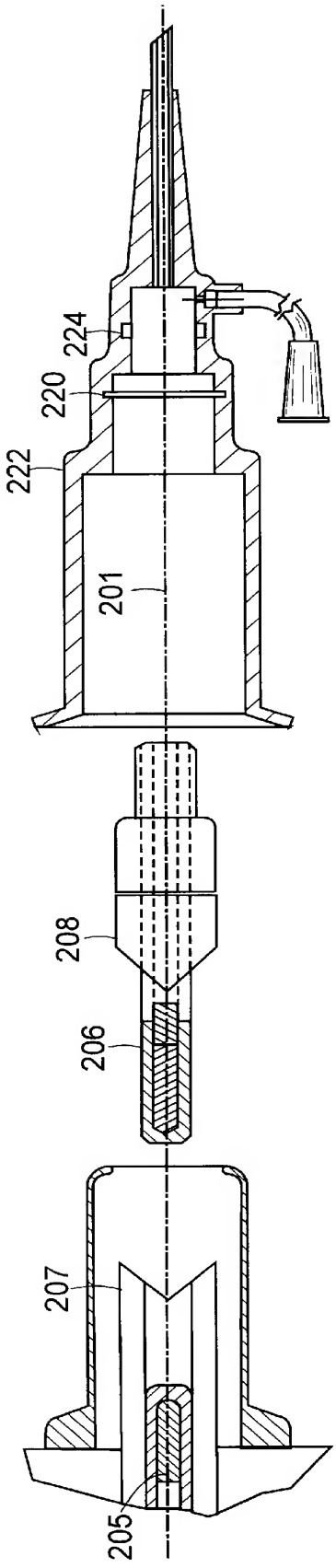


FIG. 12

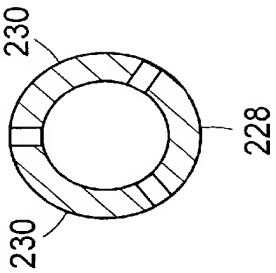


FIG. 11

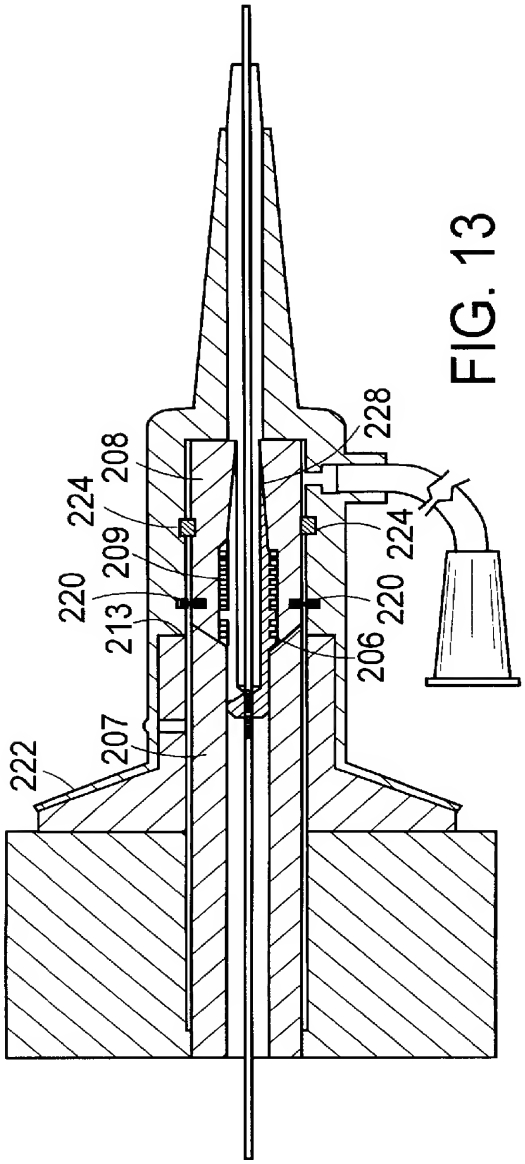


FIG. 13

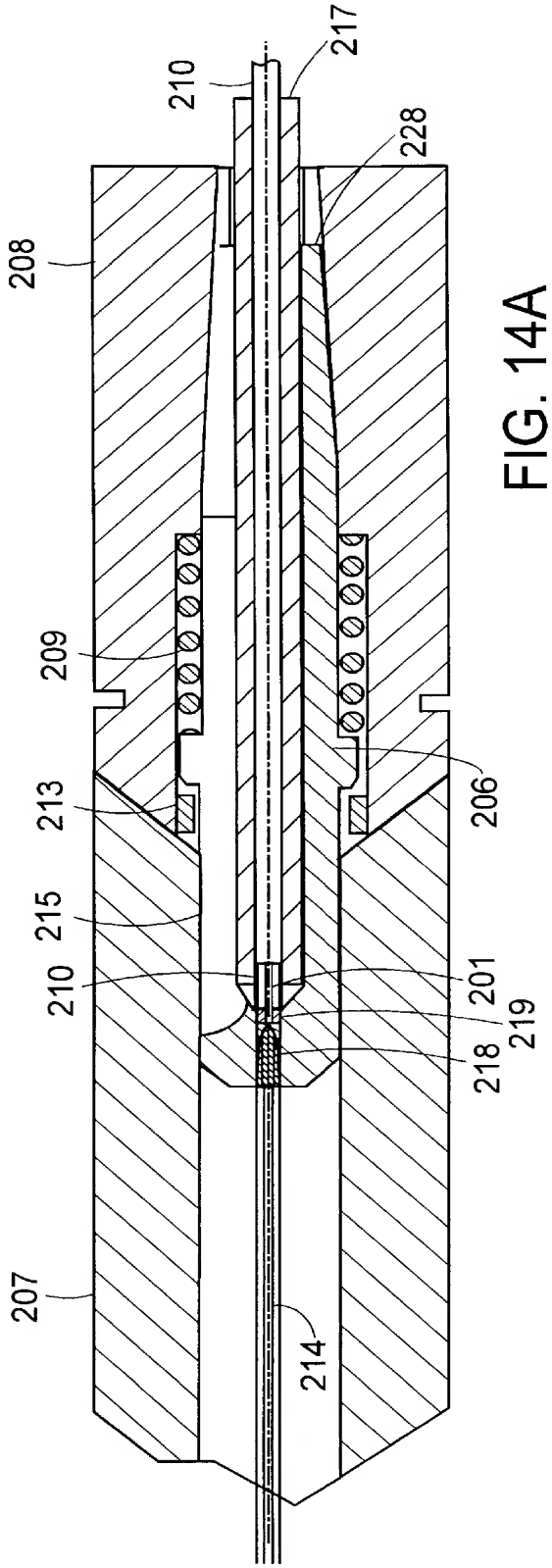


FIG. 14A

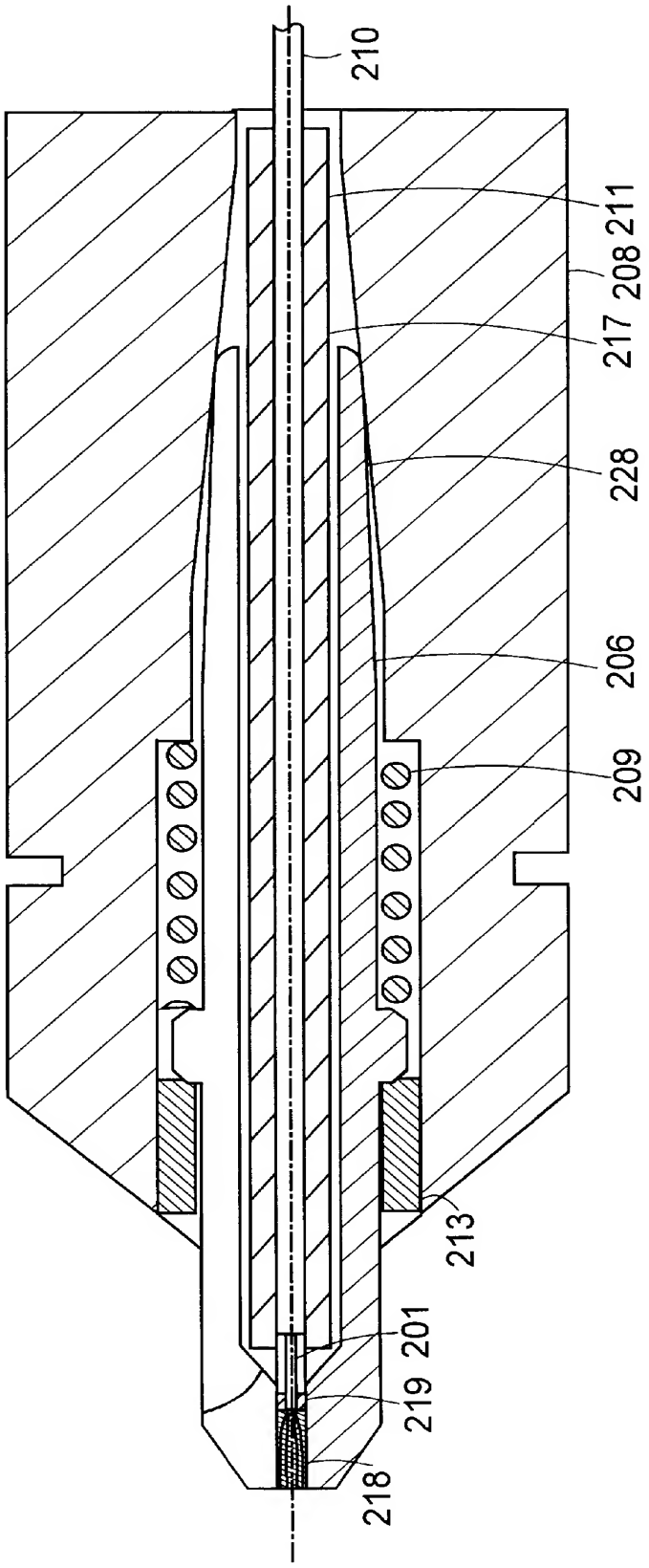


FIG. 14B

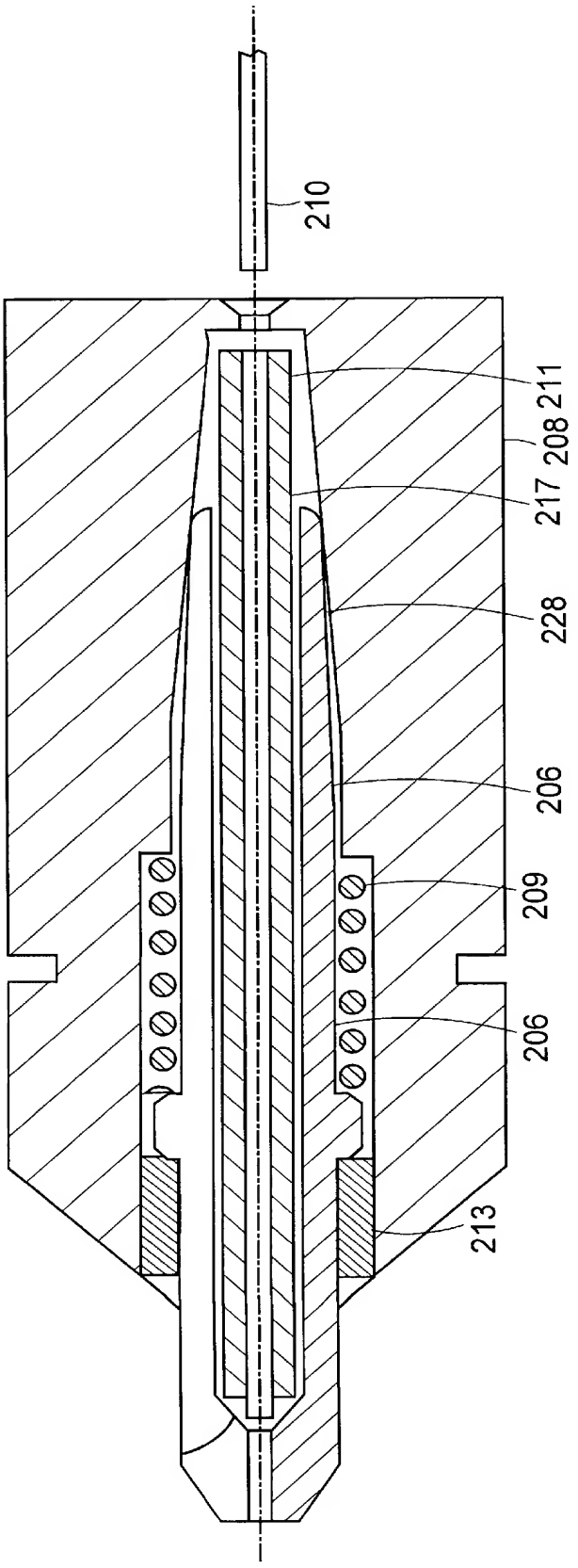


FIG. 14C

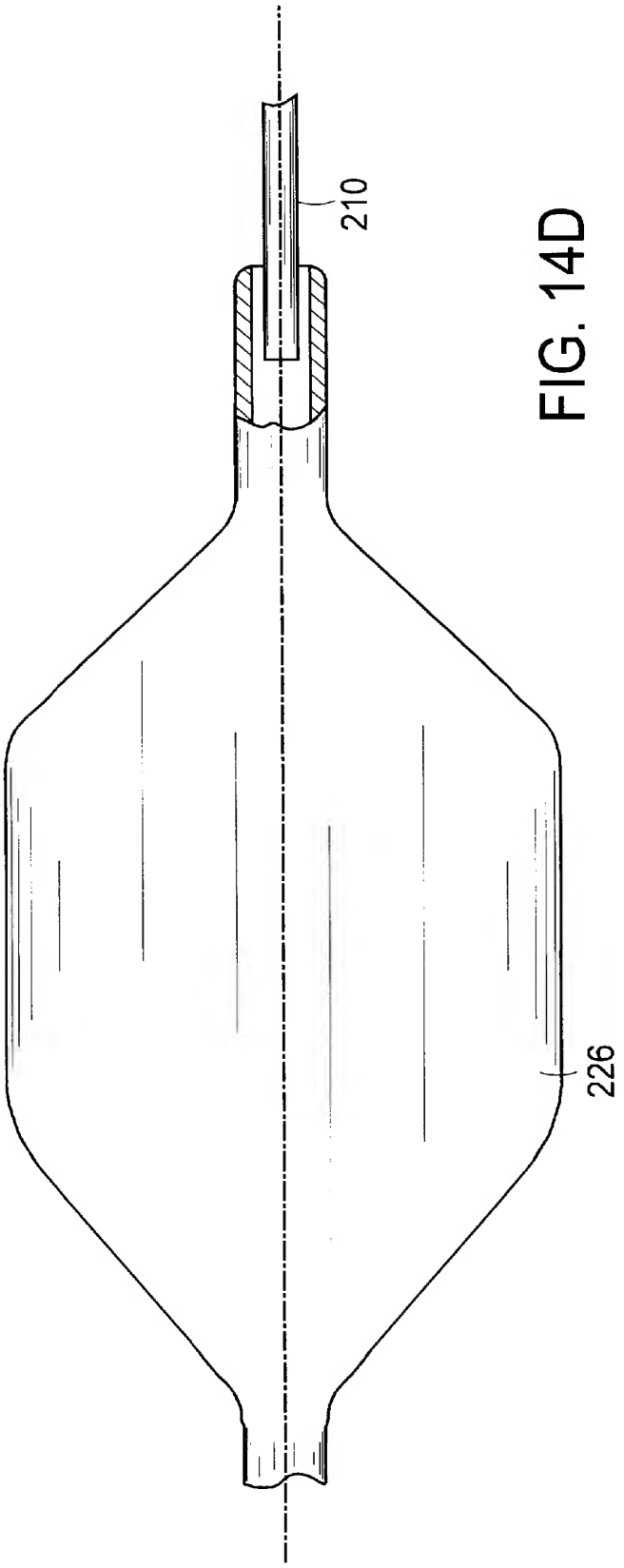
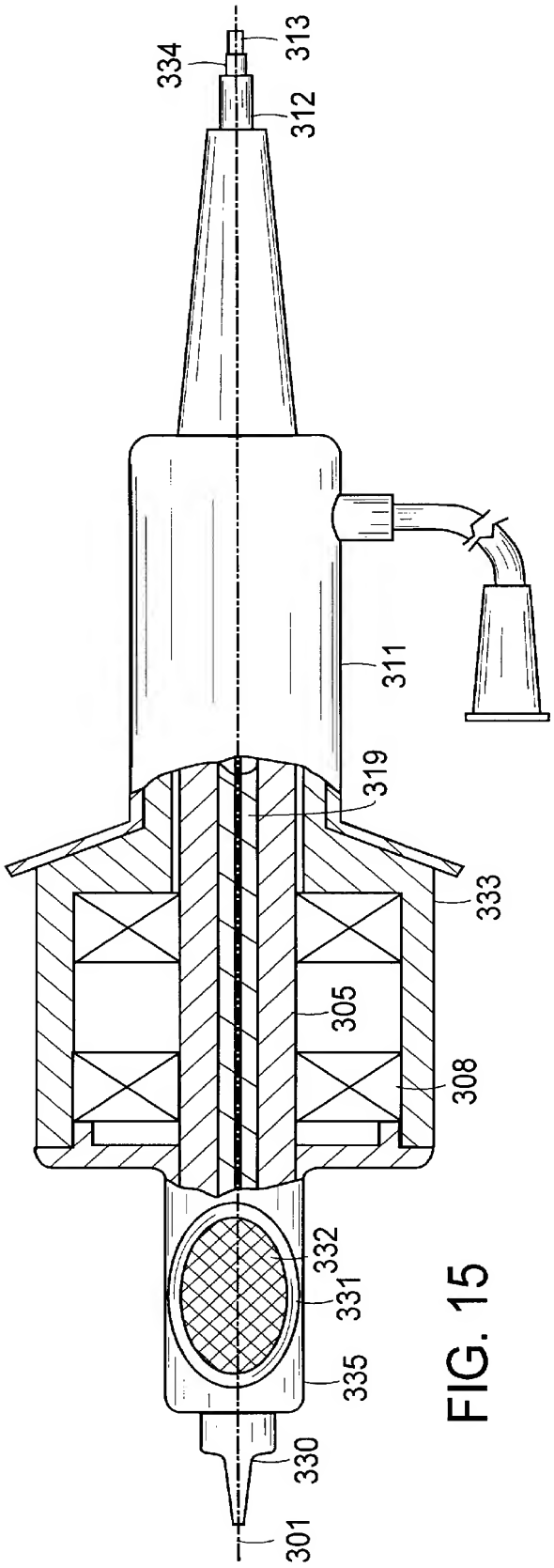


FIG. 14D


334
313
312
311
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305
308
332
331
335
330
301

FIG. 15

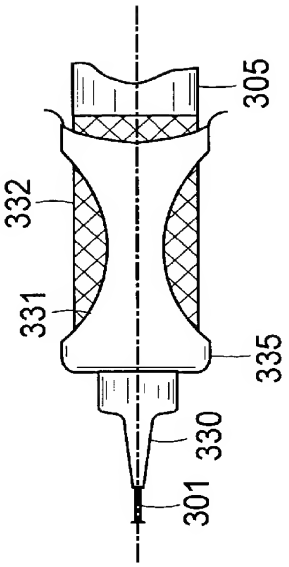
305
332
331
335
330
301

FIG. 16

ROTATABLY CONNECTING OPTICAL FIBERS

This application is a divisional of application Ser. No. 08/758,146, filed Nov. 25, 1996 now U.S. Pat No. 5,872,879.

BACKGROUND OF THE INVENTION

This invention relates to connectors for connecting a rotatable optical fiber to a rotor shaft while maintaining the rotatable optical fiber in axial alignment with a stationary optical fiber.

Certain medical procedures such as in-vivo optical biopsy and optical coherence tomography (OCT) utilize diagnostic and interventional devices in conjunction with optical fibers that provide optical feedback to the clinician. The optical fibers are attached to an imaging console that displays an image or a processor that interprets data. Potential applications of such systems are stationary tissue spectroscopy of polyps and other mucosal tissues, linear scans of various portions of the human anatomy, and cross-sectional images of tubular vessels such as arteries, the gastrointestinal tract, urological structures, the biliary tree, and neurological vessels.

Procedures such as tissue spectroscopy typically utilize an endoscope, cystoscope, colonoscope, or sigmoidoscope for direct visual feedback. The scope helps direct a biopsy device to a site of interest, such as a polyp or dysplastic or cancerous tissue, and also provides a working channel for the biopsy device, a light source, and an optical path for visual guidance. Other procedures involving optical feedback use trocars for direct access to some parts of the anatomy, such as the breast for breast biopsies, or other areas inaccessible through an orifice.

SUMMARY OF THE INVENTION

One aspect of the invention features a connection system that includes an interventional medical device having a rotatable optical fiber, an assembly having a conduit for conveying a light beam to the rotatable fiber, and a coupling. The coupling has a rotatable portion attachable to a proximal end of the rotatable fiber, and a stationary portion attachable to the assembly that includes the light beam conduit so as to permit the rotatable fiber to rotate while its proximal end remains in axial alignment with the light beam.

According to another aspect of the invention the assembly having the light beam conduit includes a rotor and a fixed housing. A drive mechanism is attached to the rotor for continuously rotating the rotor. The stationary portion of the coupling is attachable to the fixed housing, and the rotatable portion is attachable to the rotor so as to permit the rotatable fiber to rotate continuously with the rotor while the rotatable fiber remains in axial alignment with the light beam.

According to another aspect of the invention the proximal end of the rotatable portion of the coupling has a vee-shaped coupling surface that complements a distal end surface of the rotor. This aspect of the invention helps to ensure that the rotary and stationary optical fibers are properly aligned so as to minimize insertion loss and return loss (Fresnel loss) by ensuring that any angular, lateral, or axial misalignment between the optical fibers is minimized.

According to another aspect of the invention the stationary portion of the coupling is a stationary shield surrounding the rotatable portion. The stationary shield is attachable to the fixed housing so as to urge the rotatable portion and the rotor together. In certain embodiments the stationary shield can automatically interlock with the stationary portion of the rotor assembly. Thus, the stationary shield can be fitted onto the stationary portion of the rotor assembly with the use of a single, sterile hand holding the stationary shield. This helps to maintain a sterile field around the patient and provides ease of use during medical procedures. Thus, the invention provides a low-cost (possible single-use), reliable, ergonomic rotary fiber-optic connector, useful in the field of percutaneous diagnostic and interventional medicine, that can be attached to a non-sterile drive motor or imaging console with one hand.

According to another aspect of the invention the rotatable fiber is disengageable from the rotatable portion of the coupling when the stationary portion of the coupling does not engage the fixed housing. Thus, the rotatable fiber and an optional catheter sheath surrounding the rotatable fiber (which may have an outside diameter of about 0.50 mm or less) can serve as a guidewire so that a catheter with a guidewire lumen or monorail tip can be passed over it.

Another aspect of the invention features a sheath surrounding the rotatable fiber and attachable to the stationary portion of the coupling, and a fluid port connected to the stationary portion of the coupling that enables introduction of fluid into the sheath and around the rotatable optical fiber.

According to another aspect of the invention the rotor is at least partially hollow and includes a bearing that holds the light beam conduit in axial alignment with the rotatable fiber when the rotatable portion of the coupling engages the rotor. Because the rotor shaft is hollow and the stationary optical fiber has a distal end portion positioned within the hollow rotor shaft, the distal end portion of the stationary optical fibers and the proximal end portion of the rotatable optical fiber can be located in the vicinity of the distal end surface of the rotor shaft and the proximal end surface of the rotatable coupling. This provides a simple configuration for quickly and easily connecting the rotatable coupling with the rotor shaft while maintaining the rotatable optical fiber in axial alignment with the stationary optical fiber. The configuration also protects the end surfaces of the optical fibers (or the lenses to which the end surfaces are connected) from damage and contaminants that would interfere with the signal.

Numerous additional objects and advantages of the invention will become apparent from the detailed description and the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of an optical catheter system.

FIG. **2** is a drawing of an optical catheter in use within a patient's body and showing a fiber-optic rotary connector detached from a fiber-optic motor assembly.

FIG. **3** is a drawing of an tissue spectroscopy snare catheter inserted into a patient's body through an endoscope and showing a fiber-optic rotary connector attached to a fiber-optic motor assembly.

FIG. **4** is a cross-sectional drawing of a fiber-optic rotary connector attached to a fiber-optic motor assembly.

FIG. **5** is a cross-sectional drawing of a fiber-optic rotary connector attached to a fiber-optic motor assembly, the motor assembly including a stationary GRIN lens longer than the stationary GRIN lens shown in FIG. **4**.

FIG. **6** is a top view of a motor coupling and a ferrule coupling, showing the use of a tool that fits the stationary and rotatable GRIN lenses within the motor coupling and ferrule coupling.

FIG. **7** is a cross-sectional side view of the motor coupling and ferrule coupling of FIG. **6**.

FIG. **8** is a cross-sectional side view of the motor coupling and ferrule coupling of FIG. **6** in engagement with each other.

FIG. **9** is a cross-sectional view of a fiber-optic rotary connector attached to a fiber-optic motor assembly, in which the proximal end of a guidewire having a rotatable fiber is disengageable from a rotatable ferrule in the rotary connector.

FIG. **10** is a detailed cross-sectional view of a portion of the rotary connector and a portion of the motor assembly shown in FIG. **9**.

FIG. **11** is a cross-sectional drawing of the rotatable ferrule shown in FIG. **10**, taken along line **11**—**11**.

FIG. **12** is an exploded view, partially in cross-section, of another rotary connector and a portion of a motor assembly, in which the proximal end of a guidewire having a rotatable fiber is disengageable from a rotatable ferrule in the rotary connector.

FIG. **13** is a cross-sectional view of a fiber-optic rotary connector and a motor assembly similar to the connector and motor assembly of FIG. **9** but including a rotatable GRIN rod lens.

FIGS. **14**A–**14**D are detailed cross-sectional views of a the rotary connector of FIG. **13** showing the steps of disengaging the proximal end of the guidewire from the rotatable ferrule in the rotary connector and inserting a catheter over the proximal end of the guidewire.

FIG. **15** is a side view, partially in cross section, of a fiber-optic rotary connector attached to a rotor assembly having a manually rotatable rotor shaft.

FIG. **16** is a top view of a portion of the rotor assembly shown in FIG. **15**.

DETAILED DESCRIPTION

With reference to FIG. **1**, the rotary optical connection systems described in detail below may be used to attach a fiber-optic imaging catheter or guidewire or a spectroscopy catheter or guidewire **36** to a drive unit **38** and to an extension optics cable **40**, by means of fiber-optic rotary connector **52**. A light source **42** provides light for illuminating tissue **44** through catheter or guidewire **36**. Catheter or guidewire **36** also conveys reflected or fluorescent light from tissue **44** back to a spectrometer or imaging system **46**. If catheter or guidewire **36** is used for tissue spectroscopy, a personal computer **48** can analyze the spectroscopic data to determine the probability of a malignancy and can print out the data and analysis on a printer **50**.

FIG. **2** shows an example of an optical coherence tomography catheter **10** introduced into a lumen **12** of a patient's body through an introducer catheter **14** so as to image a region of interest **16**. Fiber-optic rotary connector **18** is shown detached from fiber-optic motor assembly **20**. FIG. **3** shows an example of a tissue spectroscopy snare catheter **22** inserted into a lumen **24** of a patient's body through a working channel **26** of an endoscope **28** so as to diagnose a polyp **30** through the use of tissue spectroscopy and possibly to remove the polyp, as is described in detail in U.S. patent application Ser. No. 08/679,425, filed Jul. 8, 1996 by Doug Daniels and entitled "Diagnosing and Performing Interventional Procedures in Vivo" the entire disclosure of which is hereby incorporated herein by reference. Fiber-optic rotary connector **32** is shown attached to a fiber-optic motor assembly or manually rotated connector **34**.

FIG. **4** illustrates a motor assembly and fiber-optic rotary connector in accordance with the invention that can be used in connection with optical coherence tomography catheters and spectroscopy catheters of the type illustrated in FIGS. **2** and **3**. A motor assembly that includes motor **106**, stationary nose piece **107**, and a rotor shaft **105** is removably connected with a fiber-optic connector that includes rotatable vee-shaped coupling **109** and stationary sterile shield **111**. Vee-shaped coupling **109** and sterile shield **111** may be disposable.

Stator fiber **101**, which may be a single-mode optical fiber, a multi-mode fiber, or an optical fiber bundle, is aligned with stator GRIN (GRadient INdex of refraction) rod lens **102**, available as, for example, Melles Griot product number #06-LGS-112. Both stator fiber **101** and stator GRIN rod lens **102** are held inside stationary tube **119**, which is in turn held within rotatable stainless-steel rotor shaft **105** by means of a bearing or bushing **120** that permits rotor shaft **105** to rotate relative to stator fiber **101** and stator GRIN rod lens **102** at speeds up to about 5000 RPM. Stator fiber **101** and stator GRIN rod lens **102** are held in close proximity with rotor GRIN rod lens **104** and rotatable fiber **113** by means of a rotor vee-shaped coupling **109** that rotates inside stationary sterile shield **111**. Vee-shaped coupling **109** is made of a biocompatible injection moldable or machined rigid material such as nylon, polycarbonate, plexiglass, PEBAX, aluminum, brass, etc., and stationary shield **111** is made of an biocompatible injection-molded elastomer such as polyethylene, polyolefin, or PEBAX, and is ETO, gamma, or EB sterilizable (preferably all three). The distal end of the stationary shield functions as a strain relief for stationary catheter sheath **112**. Catheter sheath **112** may be manufactured of an inexpensive, biocompatible material such as polypropylene, polystyrene, polyethylene, nylon, PEBAX, or PET. Rotatable fiber **113** is contained with a rotatable driveshaft **134** inside stationary catheter sheath **112** (for purposes of visual clarity the distal ends of catheter sheath **112** and rotatable driveshaft **134** are shown cut away in FIG. **4**). Rotatable driveshaft **134** ensures uniform rotation at the distal tip of rotatable fiber **113**.

In one particular embodiment stator fiber **101** and rotatable fiber **113** are multiple-fiber bundles having a diameter of approximately 50 μm (0.0020 inches). The use of multiple-fiber bundles provides high flexibility and throughput. The fibers may be silica or plastic methylmethacrylate fibers with a numerical aperture of about 0.2–0.8. Single-mode optical fiber core sizes typically range from 70 μm (0.0025 inches) in diameter to 110 μm (0.0045 inches) in diameter, with the outer diameter of the fiber typically being about 125 μm (0.0050 inches). Single-mode optical fibers, which are generally used, for example, in optical coherence tomography, generally require more demanding and precise alignment than multi-mode optical fibers.

A stainless steel retaining spring clip **110** holds floating vee-shaped coupling **109** inside stationary sterile shield **111**, and curved low-friction felt-fiber or TEFLON or Belleville washer **116** located between polished surfaces of vee-shaped coupling **109** and stationary shield **111** applies a small force (indicated by arrow **117**) to keep rotor GRIN rod lens **104** and stator grin rod lens **102** in close proximity with each other during rotation. The force also keeps rotor shaft **105** and rotor vee-shaped coupling **109** in contact with each other during rotation. This contact maintains the proper gap **118** between stator GRIN rod lens **102** and rotor GRIN rod lens **104** to minimize light loss. An index of refraction matching gel could be used in gap **118**. A bearing **108** is positioned between stationary, molded nose piece **107** and

rotor vee-shaped coupling **109**. Stationary nose piece **107** may be made of rigid, injection-molded polymer such as polycarbonate or from machined metal.

In one embodiment there is an interference fit between stationary shield **111** and the stationary nose piece **107** that automatically interlocks stationary shield **111** and stationary nose piece **107** when stationary shield **111** is slidably inserted over stationary nose piece **107**. In other embodiments stationary shield **111** and stationary nose piece **107** include interlocking elements that engage each other to automatically interlock stationary shield **111** and stationary nose piece **107**. For example, a ball plunger **124**, or alternatively a spring plunger, may be provided between stationary shield **111** and nose piece **107**. The ball plunger or spring creates an audible "click" when stationary shield **111** is properly interlocked with nose piece **107**.

Luer adapter sidearm **114** is used with a conventional syringe to introduce fluid into the central lumen of catheter sheath **112** around rotor fiber **113**, or into a separate lumen disposed within catheter sheath **112** alongside the optics lumen. Luer adapter sidearm **114** allows a slow drip or a strong flush to rinse away clots or other contaminants from a distal lens (not shown) at the distal end of rotor fiber **113** to facilitate cleaning of the lens. Also, an optically clear liquid such as saline solution can be injected into a vessel or area of interest through luer adapter sidearm **114**. Alternatively, a coupling medium or a drug may be introduced through the luer adapter sidearm. O-ring **115**, made of soft silicone, rubber or TEFLON, provides a seal between the polished surfaces of vee-shaped coupling **109** and stationary shield **111** to prevent fluid from passing into motor **106**.

In FIG. **5**, a GRIN rod lens **102** that is longer than the one shown in FIG. **4** extends through rotor shaft **105**. The nature of GRIN rod lens **102** allows custom geometries that yield various desired results. In the case of FIG. **5**, for example, GRIN lens **102** accepts light emanating from stator optical fiber **101**, then bends the light into a sinusoidal path **103** through exactly 1 and ½ cycles, so that when the light exits the distal end of lens **102** it is collimated. In FIG. **4**, in which the length of GRIN lens **102** is minimized, GRIN lens **102** bends the light into a sinusoidal path **103** through exactly ½ cycle. The collimated light that enters rotor lens **104** is then focused into rotor optical fiber **113** with minimized losses. By positioning rotor GRIN rod lens **104** within 0.001–0.005 inches from the matching distal face of stator lens **102** of FIG. **4** or FIG. **5**, light loss is minimized. The use of GRIN rod lenses **102** and **104** reduces the need for precise alignment of optical fibers **101** and **113**. This is especially important if the optical fibers are single-mode fibers. GRIN rod lenses **102** and **104** may be made of silica having fluoride-doped outer layers. GRIN rod lens **104** may be disposable along with vee-shaped coupling **109** and stationary shield **111**. A detailed description of GRIN rod lenses can be found in U.S. Pat. No. 4,641,915.

FIGS. **6–8** show one particular construction of a rotor shaft **105** and vee-shaped coupling **109** (note that the elements shown in FIGS. **6–8** have somewhat different dimensions and shapes than the corresponding elements shown in FIGS. **4** and **5**). Rod-like tool **121** is used to insert GRIN lens **102** into tube **119**, and rod-like tool **122** is used to insert GRIN **104** into vee-shaped coupling **109**. An index-matching ultraviolet-cured epoxy fills the slight gap **125** between GRIN lens **102** and spacer **123** and the slight gap between GRIN lens **104** and vee-shaped coupling **109** at the end of optical fiber **113**. The distal end surface **127** of tube **119** acts as a stop that engages a complementary proximal end surface of vee-shaped coupling **109** as is shown in FIG. **8**. Rod-like tool **121** sets the surface of GRIN lens **102** about 0.0010 inches from the distal end surface of tube **119**, and rod-like tool **122** sets the surface of GRIN lens **104** flush with the C-bore **129** of vee-shaped coupling **109**. When vee-shaped coupling **109** is mated with rotor shaft **105**, tube **119** bottoms into the counterbore in vee-shaped coupling **109**, leaving a 0.0010-inch gap between the GRIN lenses. The male and female vee shapes of vee-shaped coupling **109** and rotor shaft **105** mate with a small gap of about 0.0030 inches clearance to provide a positive drive system without binding or overtravel.

FIGS. **9** and **10** show a motor assembly and fiber-optic connector similar to those disclosed in FIGS. **4** and **5** except that rotor fiber optic core **201** and its metallic or plastic sleeve or sheath **210** form an optical guidewire that can be disengaged from a vee-shaped coupling **208**, so that a catheter with a guidewire lumen or monorail tip can be passed over the optical guidewire. Rotor ferrule **206** and stator ferrule **211** align fiber optic cores **201** and **205**, both in terms of lateral offset and angular alignment, thereby reducing optical loss at a butt joint **203** between the two fiber optic cores.

Vee-shaped coupling **208** attaches the optical guidewire to rotor shaft **207** in a manner similar to FIGS. **4** and **5** above. The embodiment of FIGS. **9** and **10** is different from the embodiments of FIGS. **4** and **5**, however, in that the medical guidewire can be detached from vee-shaped coupling **208** and ferrule **206**. The proximal end of the optical guidewire has an outer diameter of less than 0.0180 inches, which is substantially the same as that of the remainder of the guidewire.

The proximal end of the guidewire is insertable into rotor ferrule **206**, which has three fingers **228**, **230**, and **232** as shown in FIG. **11** (one finger **228**, is shown in cross-section in FIG. **10**). Fingers **228**, **230**, and **232** clamp onto a centering and gripping tube **217** by means of collet closing action. This collet closing action of rotor ferrule **206** occurs as the rotor ferrule is inserted into the central bore **215** of rotor shaft **207** and engages the end of stator ferrule **211** (i.e., when the rotary connector is engaged with the motor assembly). When this happens, the internal taper of vee-shaped coupling **208** closes rotor ferrule **206** onto the centering and gripping tube **217**, which is made of a soft, supple material such as silicone rubber or PEBAX. This gripping force holds sleeve or sheath **210** of the stiff guidewire concentric with stator fiber optic core **205**, and thus sleeve or sheath **210** helps attain the proper axial and angular alignment of rotor fiber optic core **201** and stator fiber optic core **205**. The distal end surface of stator ferrule **211** includes a circumferential ridge **212** that engages the proximal end surface of rotor ferrule **206** to ensure that the rotor and stator optical fibers are in lateral and angular alignment with each other.

Retainer ring **213** retains rotor ferrule **206** inside vee-shaped coupling **208**. A compression spring **209** pushes rotor ferrule **206** toward stator ferrule **211** to force the two ferrules to engage each other, thereby maintaining the proper gap between the rotor and stator optical fibers **201** and **205**. When vee-shaped coupling **208** is detached from the motor assembly, compression spring **209** pushes rotor ferrule **206** all the way toward retainer ring **213**, thereby resulting in collet opening action of rotor ferrule **206**. This enables the guidewire to be detached from the motor and stationary optical fiber **201** and used as an ordinary guidewire without a bulky connector.

A stainless steel retaining spring clip **220** holds floating vee-shaped coupling **208** inside stationary sterile shield **222**.

Sterile shield **222** slides along the guidewire as it is removed from rotor ferrule **206** and vee-shaped coupling **208**. O-ring **224** provides a seal between the polished surfaces of vee-shaped coupling **208** and stationary shield **222** to prevent fluid from passing into the motor.

FIG. **12** shows an exploded view of another rotary connector and a portion of a motor assembly similar to the rotary connector and motor assembly of FIGS. **9** and **10** but having slightly different dimensions and shapes of rotor ferrule **206**, vee-shaped coupling **208**, and stationary shield **222**.

FIGS. **13** and **14**A-D show a motor assembly and fiber-optic connector similar to those disclosed in FIGS. **9** and **10** except that the optical guidewire includes a rotor GRIN rod lens **218** having an outer diameter of about 0.0150 inches. The rotor GRIN rod lens reduces the need for high machine tolerances in the components of the rotary connector and the motor assembly. The rotor GRIN rod lens **218** in the guidewire receives a collimated light beam **214** and focuses it into rotor fiber optic core **201**. This configuration allows the optical fiber to receive a collimated light beam **214** generated by any suitable collimated light source or any means of generating a collimated light beam, such as a stator GRIN rod lens, a laser, a laser diode, etc. If a stator GRIN rod lens is used to generate the collimated light beam, the stator GRIN rod lens may be located at the proximal end of the motor assembly, such that the stator GRIN rod lens and the rotor GRIN rod lens **218** are separated by a relatively large gap to simplify the process of mating the rotary connector and the motor assembly. The stator GRIN rod lens may be mounted either on the same axis as the rotor GRIN rod lens, or it may be mounted normal to the axis of the rotor GRIN rod lens provided that a mirror or beamsplitter is used to direct the collimated light beam onto the axis of the rotor GRIN rod lens **218**.

Rotor GRIN rod lens **218** is mounted at the proximal end of the optical guidewire in a process that optimizes the fiber-to-lens interface and throughput. In particular, the rotor GRIN rod lens is mounted concentrically with rotor optic fiber core **201** via a doughnut-shaped alignment disk **219** using ultraviolet-curable epoxy. Then rotor fiber optic core **201** is inserted into guidewire sleeve or sheath **210**.

In FIG. **14**A the rotary connector is engaged with the motor assembly, and the fingers of rotor ferrule **206** are clamped onto centering and gripping tube **217**, due to the internal taper of vee-shaped coupling **208**. In FIG. **14**B, the rotary connector has been dis-engaged from the motor assembly, and the fingers of rotor ferrule **206** are open, thereby making it possible to remove the guidewire from the rotor ferrule as shown in FIG. **14**C. After the guidewire has been removed from the rotor ferrule, a catheter such as the balloon catheter **226** shown in FIG. **14**D can be inserted over the proximal end of the guidewire.

FIGS. **15** and **16** show an alternative embodiment in which the rotor assembly is a hand-held connector **333** having a manually rotatable rotor shaft **305**. Stator optical fiber **301** is supported by strain relief **330**, which is attached to proximal end cap **335** of hand-held connector **333**. End cap **335** is fixedly joined to stator ferrule **319**, which holds stator optical fiber **301** (and optionally a stator GRIN rod lens at the distal end of fiber **301**) in a rotationally stationary position. End cap **335** includes two cutouts **331** on opposite sides of end cap **335** to allow finger access to knurled portion **332** of rotor shaft **305**. Rotor shaft **305** is held concentrically within hand-held connector **333** by bearings **308**. A sterile barrier **311** automatically interlocks with hand-held connector **333** in the manner described above in connection with FIG. **4**. Rotor optical fiber **313** is contained within rotary driveshaft **334**, which is housed in sheath or catheter **312** (for purposes of visual clarity the distal ends of catheter sheath **312** and rotatable driveshaft **334** are shown cut away in FIG. **15**). Driveshaft **334** ensures uniform rotation at the distal tip of rotor fiber **313**. This hand-rotated embodiment can include a single rotatable GRIN rod lens as described above in connection with FIGS. **13** and **14**A–**14**D.

There has been described new and useful connectors for connecting a rotatable optical fiber to a rotor shaft while maintaining the rotatable optical fiber in axial alignment with a stationary optical fiber. It will be apparent to those skilled in the art that numerous modifications of and departures from the specific embodiments described herein are possible without departing from the inventive concepts.

What is claimed is:

1. A connection system comprising:

a rotatable optical fiber;

an assembly comprising a conduit for conveying a light beam to the rotatable fiber; and

a coupling having a rotatable portion attachable to a proximal end of the rotatable fiber, and a stationary portion attachable to the assembly comprising the light beam conduit so as to permit the rotatable fiber to rotate while its proximal end remains in axial alignment with the light beam, the rotatable fiber being disengageable from the rotatable portion when the stationary portion does not engage the assembly comprising the light beam conduit.

2. The connection system of claim **1** wherein the rotatable fiber is non-disengageable from the rotatable portion when the stationary portion engages the assembly comprising the light beam conduit.

3. The connection system of claim **1** wherein the rotatable portion comprising a ferrule with which the rotatable portion attaches to the proximal end of the rotatable fiber.

4. The connection system of claim **3** wherein the ferrule attaches to the proximal end of the rotatable fiber by collet closing action when the stationary portion of the coupling engages the assembly comprising the light beam conduit.

5. The connection system of claim **3** further comprising a spring positioned within the rotatable portion of the coupling that forces the ferrule toward the rotatable stator.

6. The connection system of claim **5** wherein the spring is compressed when the stationary portion of the coupling engages the assembly comprising the light beam conduit.

7. The connection system of claim **1** further comprising a sleeve surrounding the rotatable fiber, the sleeve and the optical fiber forming an optical guidewire.

8. The connection system of claim **7** wherein the sleeve is rotatable with the rotatable fiber.

9. A connection system comprising:

a rotatable optical fiber;

a sheath surrounding the rotatable fiber

an assembly comprising a conduit for conveying a light beam to the rotatable fiber;

a coupling having a rotatable portion attachable to a proximal end of the rotatable fiber, and a stationary portion attachable to the sheath and the assembly comprising the light beam conduit so as to permit the rotatable fiber to rotate while its proximal end remains in axial alignment with the light beam; and

a fluid port connected to the stationary portion that enables introduction of fluid into the sheath and around the rotatable optical fiber.

10. The connection system of claim 9 further comprising a fluid port sidearm connected to the fluid port.

11. The connection system of claim 9 further comprising a seal located between the rotatable and stationary portions of the coupling that substantially prevents the fluid from passing toward the assembly comprising the light beam conduit.

12. A connection system comprising:

a rotatable optical fiber;

an assembly comprising a rotor, a fixed housing, and a conduit for conveying a light beam to the rotatable fiber;

a coupling comprising a stationary portion and a rotatable portion, the stationary portion being attachable to the fixed housing, the rotatable portion being attachable to a proximal end of the rotatable optical fiber and to the rotor so as to permit the rotatable fiber to rotate with the rotor while the rotatable fiber remains in axial alignment with the light beam;

the rotor being at least partially hollow and comprising a bearing that holds the light beam conduit in axial alignment with the rotatable fiber when the rotatable portion of the coupling engages the rotor.

13. The connection system of claim 12 wherein the light beam conduit comprises a stationary optical fiber having a distal end portion positioned within the hollow rotor shaft.

14. The connection system of claim 1 wherein the coupling further comprises a lens assembly coupled to a proximal end of the rotatable fiber.

15. The connection system of claim 14 wherein the conduit comprises a stationary fiber, and the lens assembly comprises a rotatable rod lens axially aligned with the proximal end of the rotatable fiber and a stationary rod lens axially aligned with a distal end of the stationary fiber.

16. The connection system of claim 9 wherein the coupling further comprises a lens assembly coupled to a proximal end of the rotatable fiber.

17. The connection system of claim 16 wherein the conduit comprises a stationary fiber, and the lens assembly comprises a rotatable rod lens axially aligned with the proximal end of the rotatable fiber and a stationary rod lens axially aligned with a distal end of the stationary fiber.

18. The connection system of claim 12 wherein the coupling further comprises a lens assembly coupled to a proximal end of the rotatable fiber.

19. The connection system of claim 18 wherein the conduit comprises a stationary fiber, and the lens assembly comprises a rotatable rod lens axially aligned with the proximal end of the rotatable fiber and a stationary rod lens axially aligned with a distal end of the stationary fiber.

* * * * *

US006497706B1

(12) **United States Patent**
Burbank et al.

(10) **Patent No.: US 6,497,706 B1**
(45) **Date of Patent: Dec. 24, 2002**

(54) **BIOPSY DEVICE AND METHOD OF USE**

(75) Inventors: **Fred H. Burbank**, Laguna Niguel; **Frank Louw**, Carlsbad; **Paul Lubock**, Laguna Niguel, all of CA (US)

(73) Assignee: **SenoRx, Inc.**, Aliso Viejo, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 28 days.

(21) Appl. No.: **09/717,176**

(22) Filed: **Nov. 16, 2000**

Related U.S. Application Data

(63) Continuation of application No. 09/477,255, filed on Jan. 4, 2000, and a continuation-in-part of application No. 09/159,467, filed on Sep. 23, 1998, now Pat. No. 6,261,241, which is a continuation-in-part of application No. 09/057,303, filed on Apr. 8, 1998, now Pat. No. 6,331,166.

(60) Provisional application No. 60/076,973, filed on Mar. 3, 1998.

(51) **Int. Cl.**[7] **A61B 18/18**; A61B 10/00

(52) **U.S. Cl.** **606/45**; 606/49; 606/50; 600/565

(58) **Field of Search** 606/41, 45, 48, 606/49, 50, 167, 170; 600/562–567

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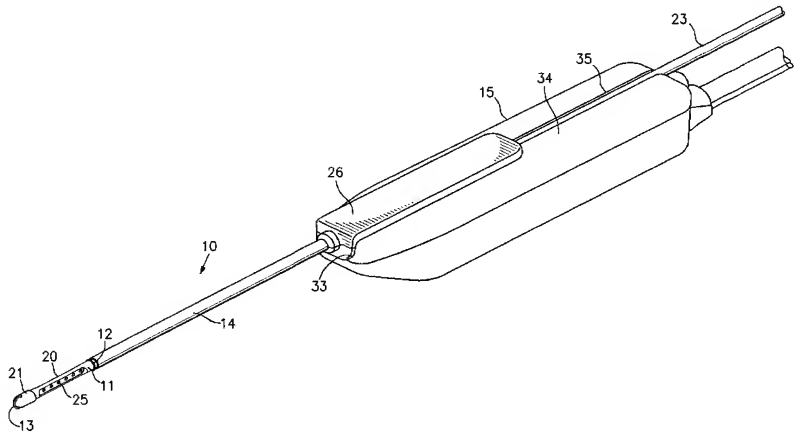
Primary Examiner—Roy D. Gibson
(74) *Attorney, Agent, or Firm*—Coudert Brothers LLP

(57) **ABSTRACT**

A device and method of using the device to access a desired tissue site within a patient's body and separating a tissue specimen from the tissue site suitable for evaluation. The device includes a probe member having an arcuate tissue cutting RF powered electrode secured to and distally spaced from the distal end of the probe and a small dimensioned distal extremity which when an inner lumen thereof is subjected to a vacuum, secured tissue for the specimen to the surface of the distal extremity. A circular RF powered cutting electrode preferably secured to and spaced from the distal end of an outer sheath which when operatively energized with high frequency electrical power and longitudinally moved along the shaft of the probe member severs the tissue specimen secured to the surface of the distal extremity of the probe member from the tissue site. The outer sheath covers the separated specimen.

19 Claims, 10 Drawing Sheets



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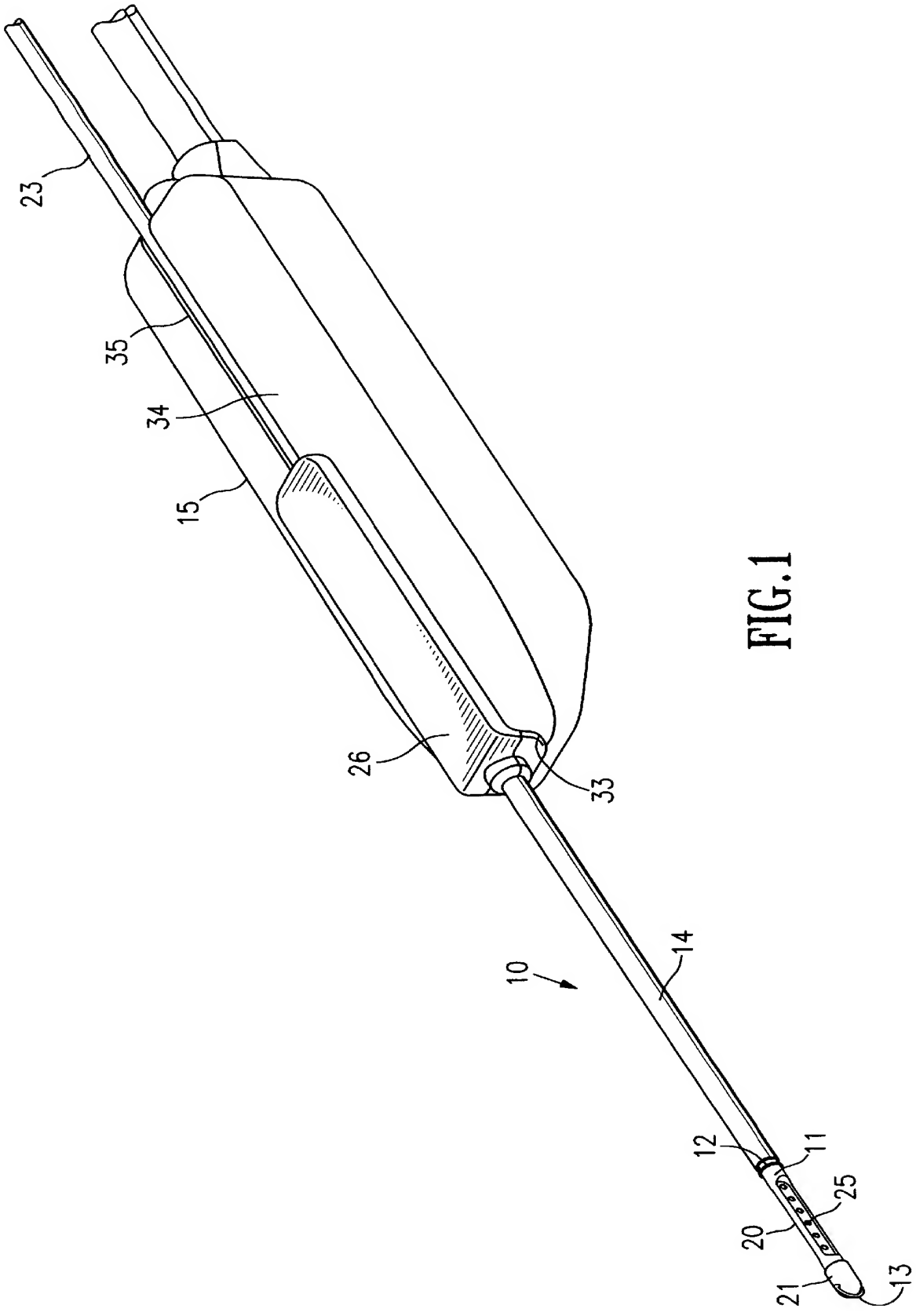

FIG.1

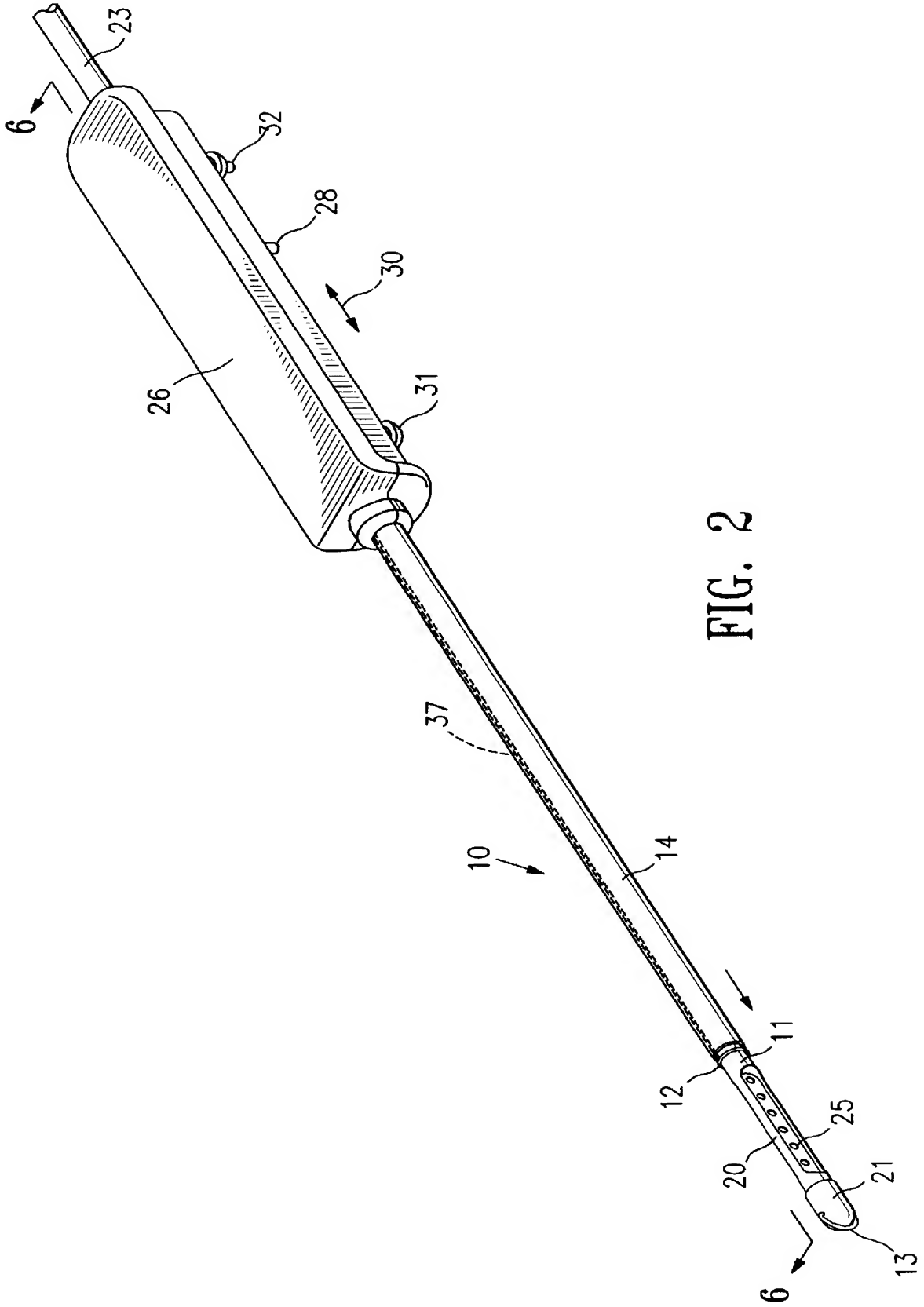

FIG. 2

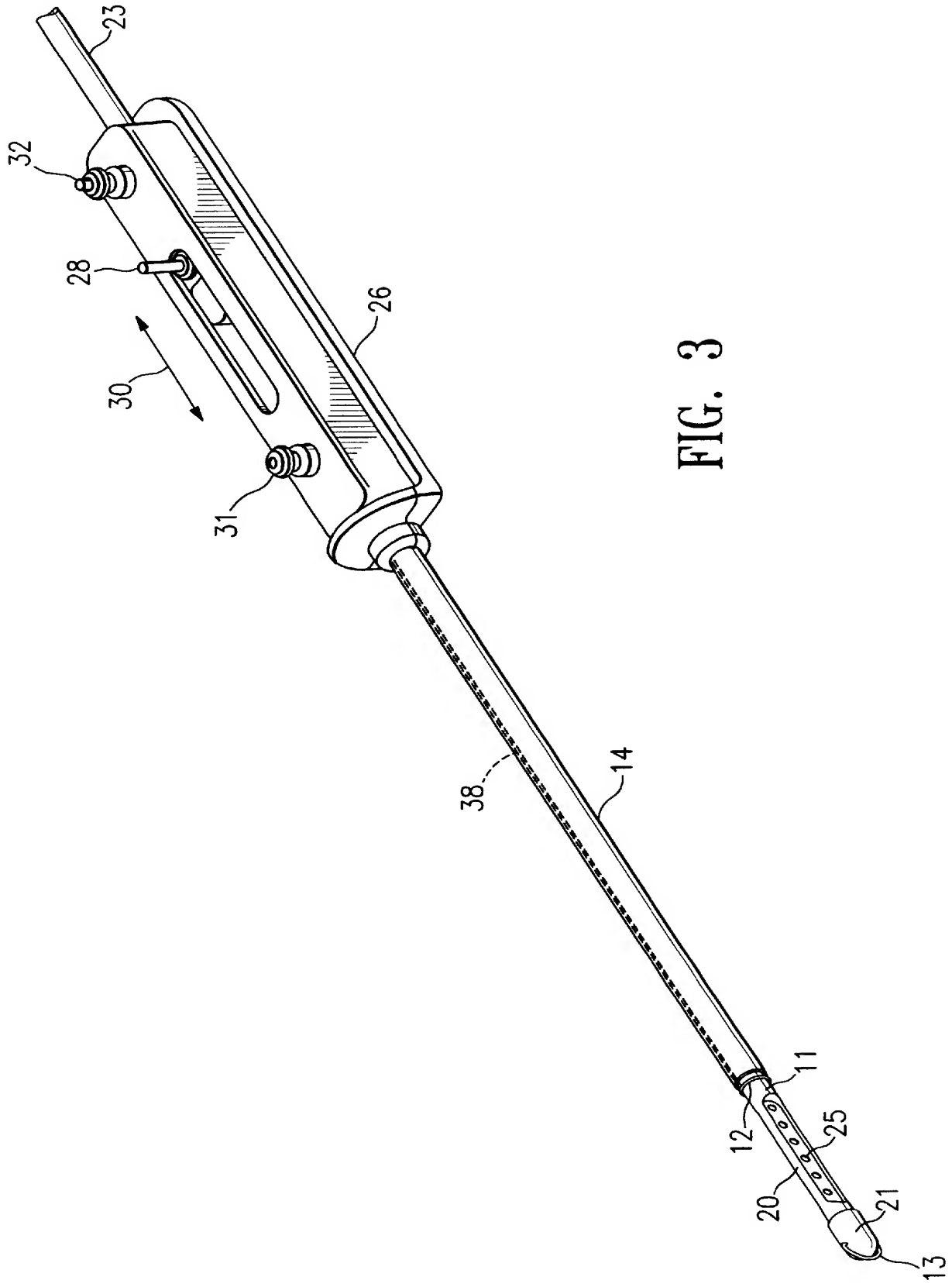

FIG. 3

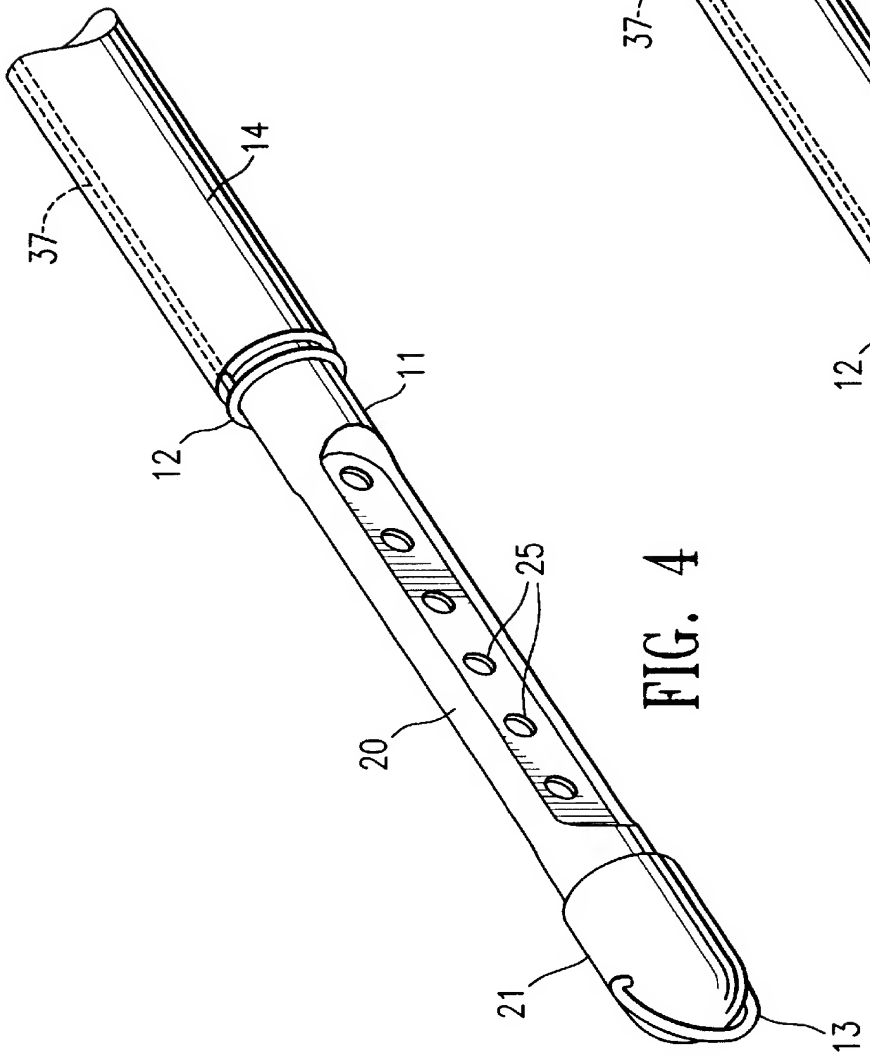

FIG. 4

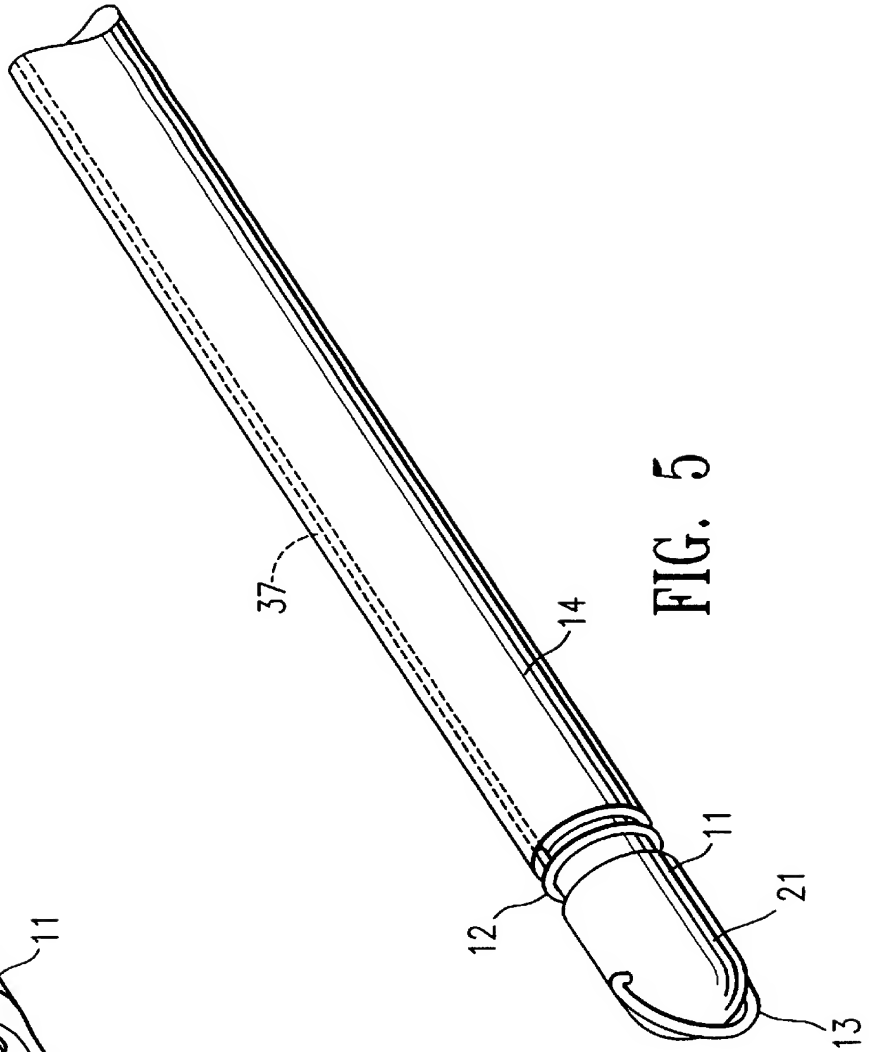

FIG. 5

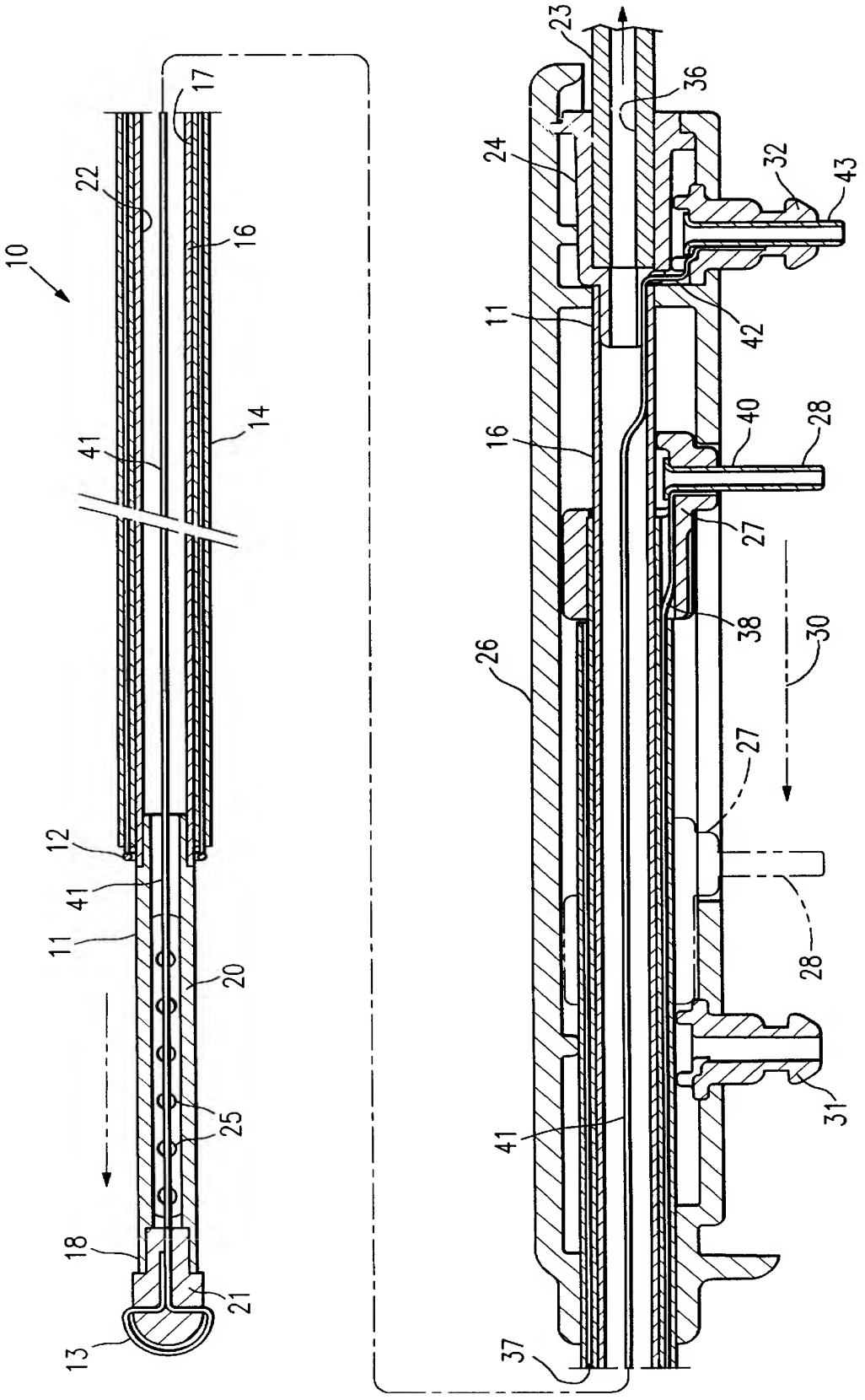
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FIG. 6

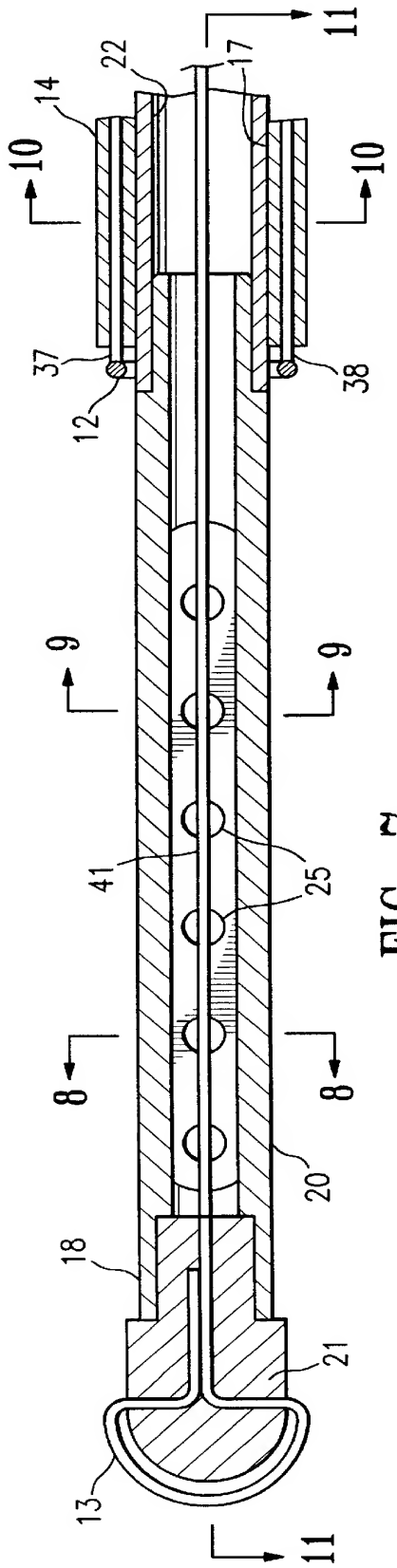


FIG. 7

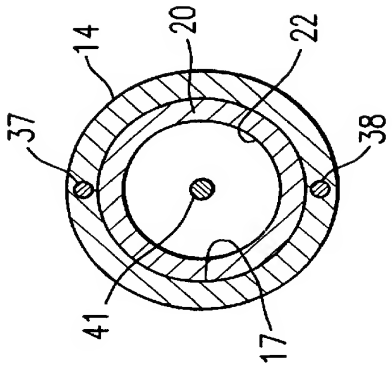


FIG. 10

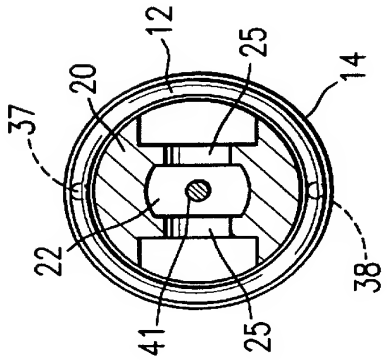


FIG. 9

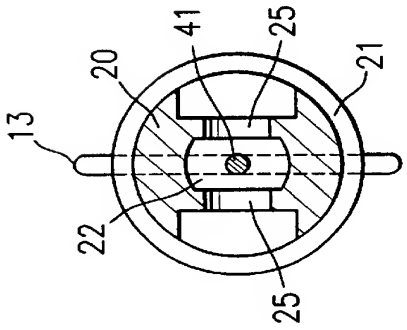


FIG. 8

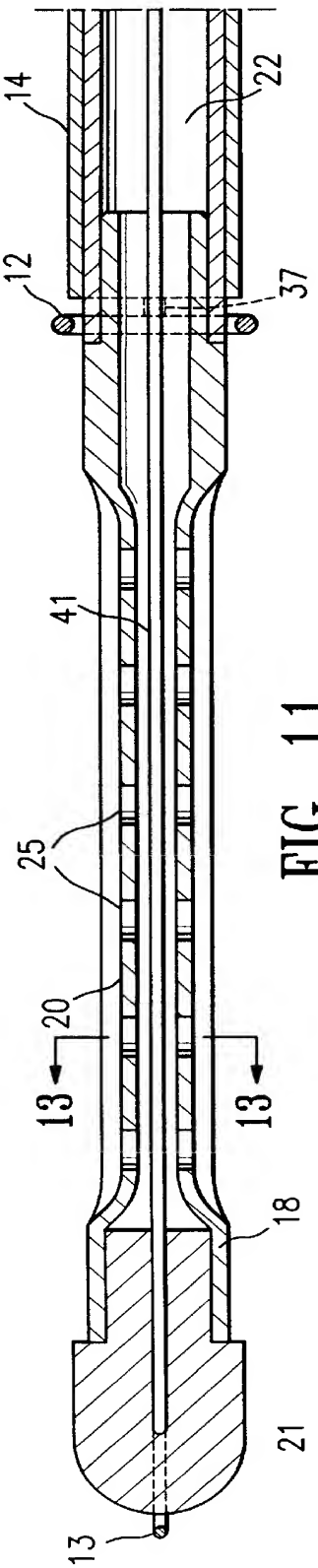


FIG. 11

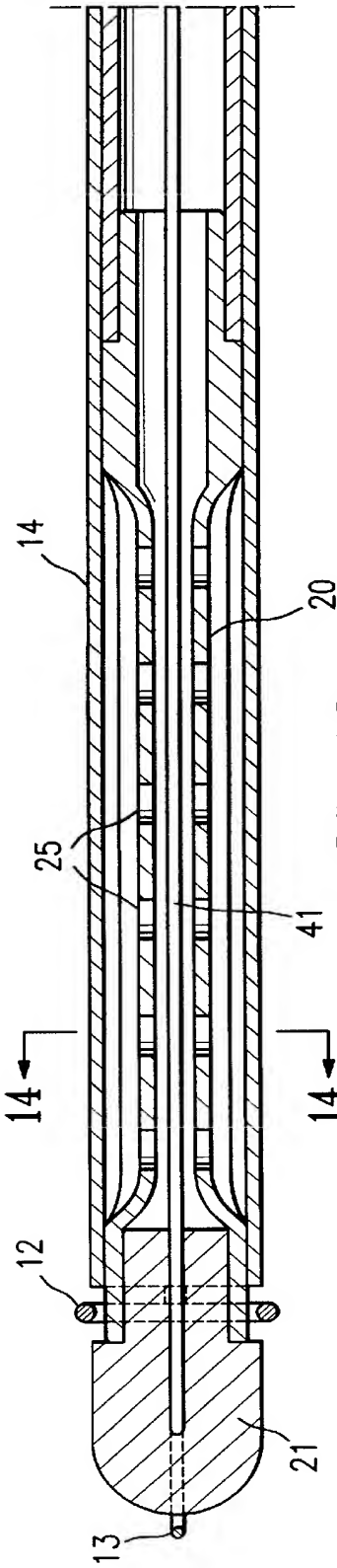


FIG. 12

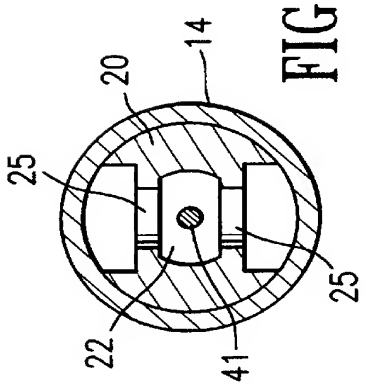


FIG. 14

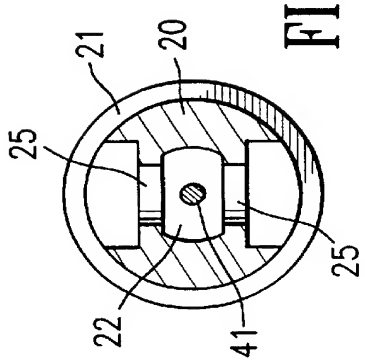
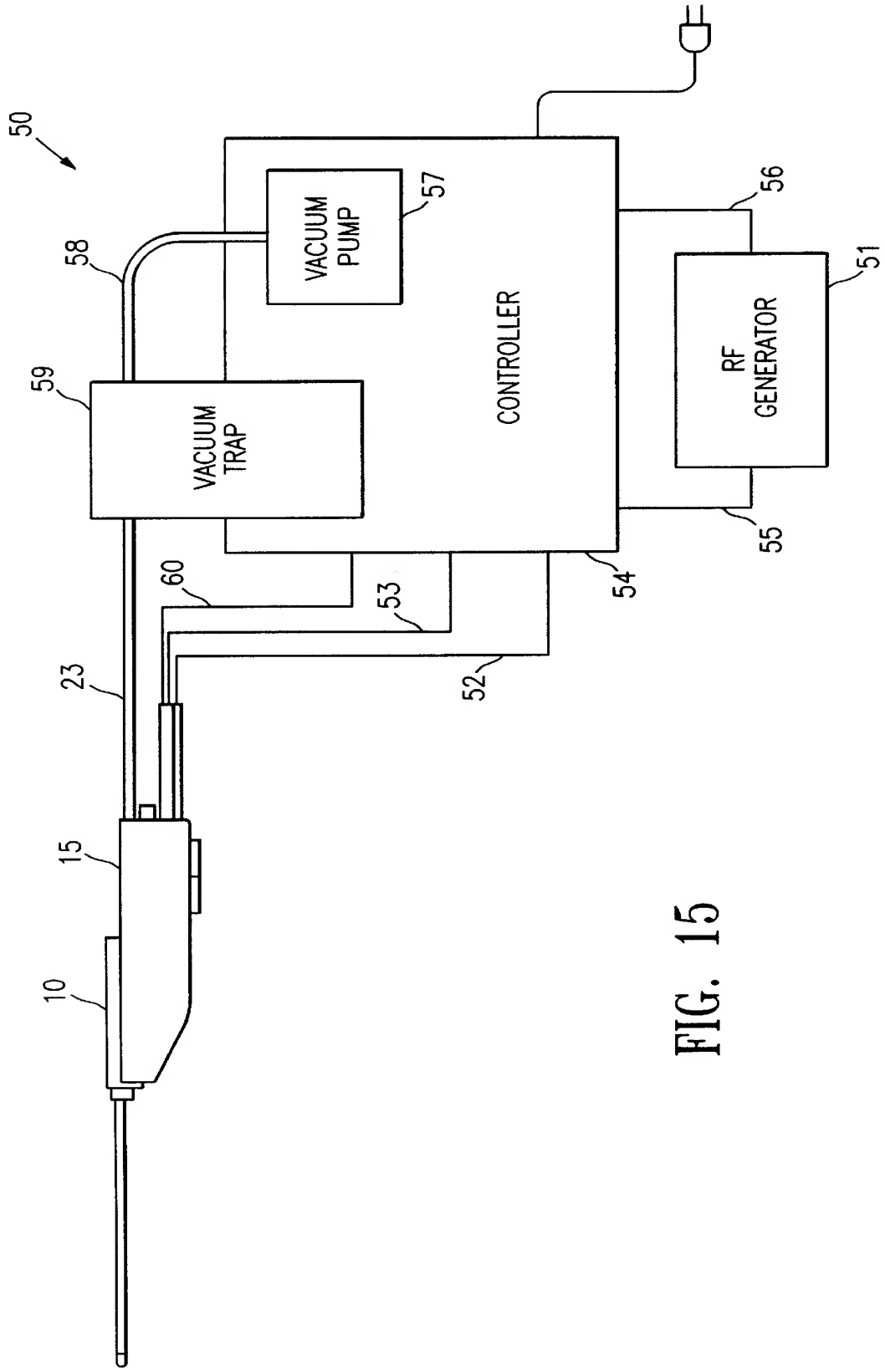


FIG. 13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VACUUM PUMP
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58
CONTROLLER
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RF GENERATOR
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59
VACUUM TRAP
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54
55
52
23
15
10

FIG. 15

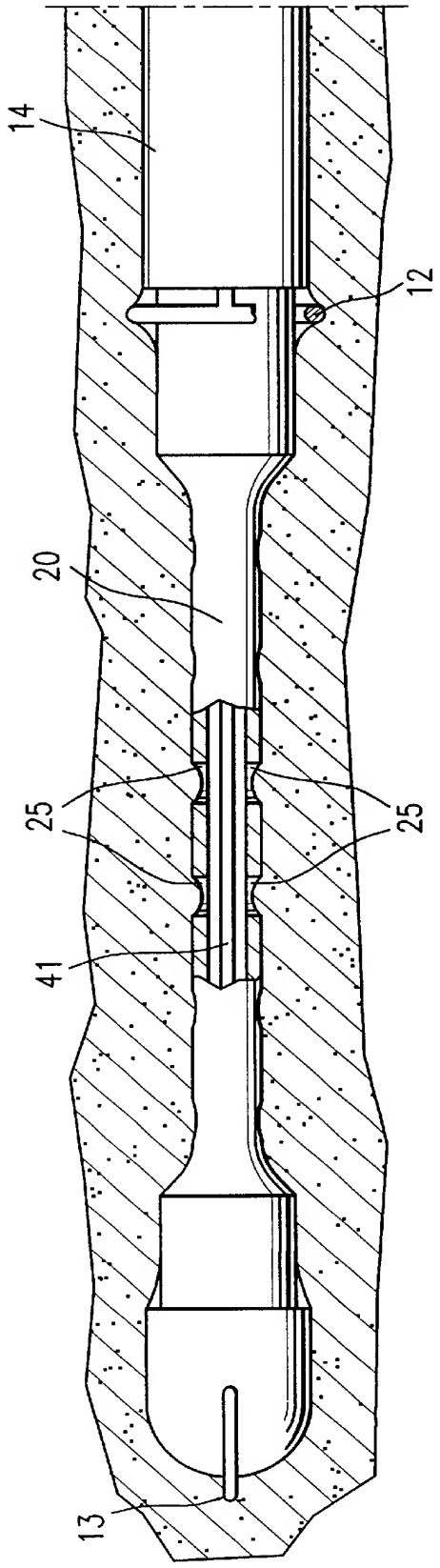

FIG. 16

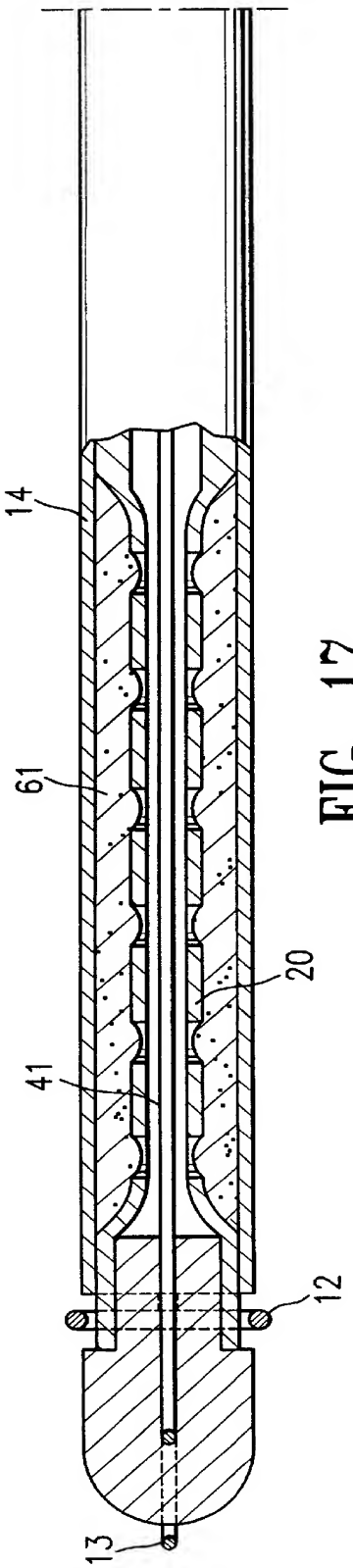

FIG. 17

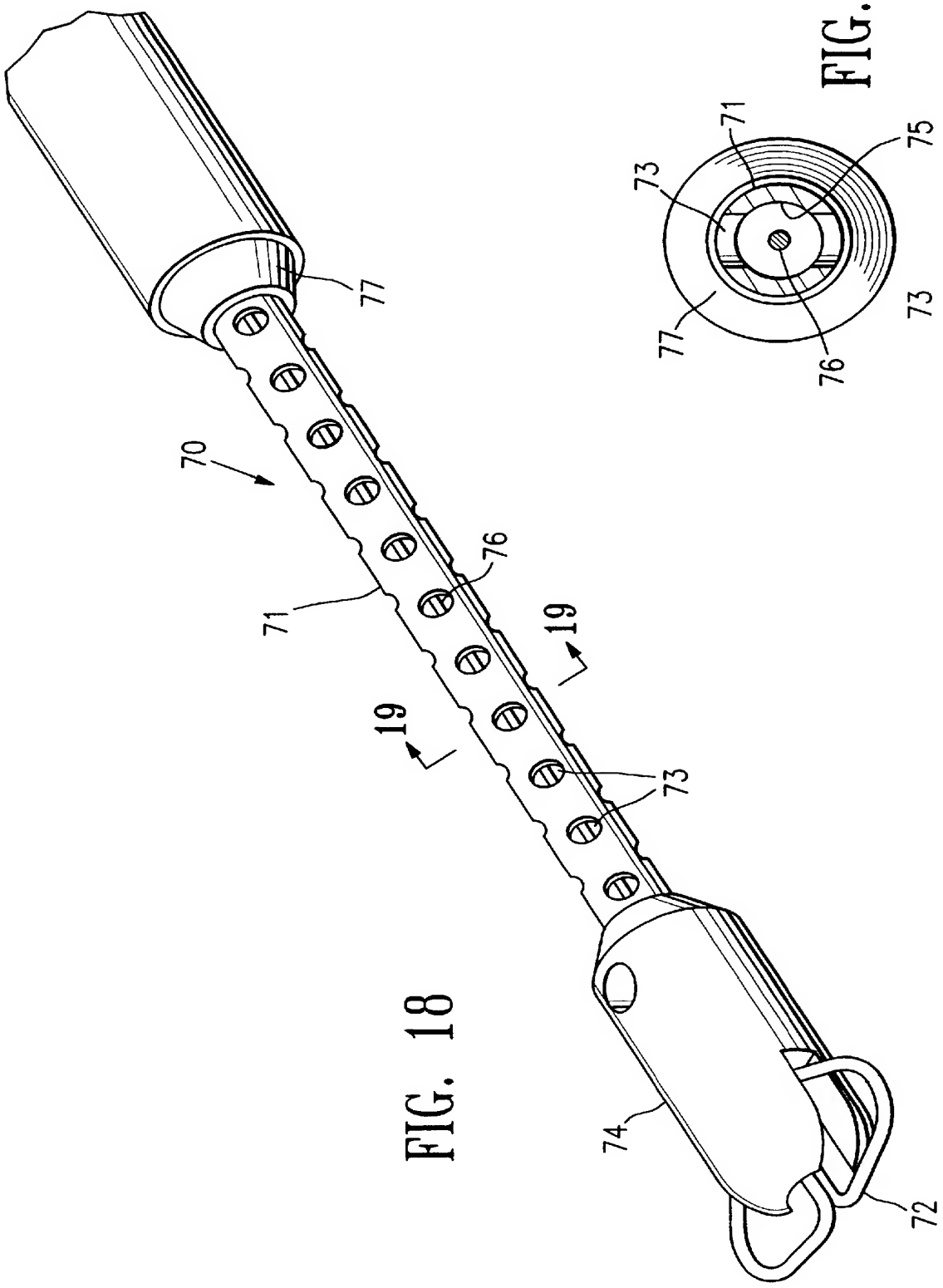

FIG. 18

FIG. 19

BIOPSY DEVICE AND METHOD OF USE

This application is a continuation-in-part of application Ser. No. 09/477,255, filed Jan. 4, 2000, and application Ser. No. 09/159,467, filed Sep. 23, 1998, now U.S. Pat. No. 6,261,241, which is a continuation-in-part of application Ser. No. 09/057,303, filed Apr. 8, 1998, now U.S. Pat. No. 6,331,166, which claims the benefit of provisional patent application Ser. No. 60/076,973, filed Mar. 3, 1998, all of which applications are hereby incorporated herein by reference in their entirety and from which priority is hereby claimed under 35 U.S.C. §§119(e) and 120.

BACKGROUND OF THE INVENTION

The present invention relates generally to the field of biopsy devices and the methods of using such devices. More specifically, it relates to a device and method for accessing a targeted site of pathologically suspect tissue mass within a patient's body, so as to facilitate the taking of a specimen of the tissue mass.

In diagnosing and treating certain medical conditions, such as potentially cancerous tumors, it is usually desirable to perform a biopsy, in which a specimen of the suspicious tissue is removed for pathological examination and analysis. In many instances, the suspicious tissue is located in a subcutaneous site, such as inside a human breast. To minimize surgical intrusion into the patient's body, it is desirable to be able to insert a small instrument into the patient's body to access the targeted site and then extract the biopsy specimen therefrom.

After removing the tissue specimens, additional procedures may be performed at the biopsy site. For example, it may be necessary to cauterize or otherwise treat the cavity which results from tissue specimen removal to stop bleeding and reduce the risk of infection or other complications. Also, it may be advantageous to mark the site for future surgical procedures should pathological tests performed on the biopsy specimen indicate surgical removal or other treatment of the suspected tissue mass from which the specimen was removed. Such marking can be performed, for example, by the apparatus and method disclosed and claimed in co-pending U.S. patent application Ser. No. 09/343,975, filed Jun. 30, 1999, entitled "Biopsy Site Marker and Process and Apparatus for Applying It," which is hereby incorporated by reference in its entirety.

Electrosurgical techniques have been used in a variety of circumstances, including certain types of biopsy procedures. In electrosurgery, high frequency electrical energy is applied through an active electrode to patient tissue. The electrical energy flows through the tissue from the active electrode to a return electrode which is in contact with the patent's tissue and which may be on the exterior of the patient's body or intracorporeally disposed. Typically, the return electrode is attached to the patient at a point remote from where the primary or active electrode contacts the tissue. The tissue adjacent the primary electrode is ablated, to form an opening in the tissue. An electrosurgical biopsy instrument is disclosed and claimed in U.S. patent application Ser. No. 09/159,467 for "Electrosurgical Biopsy Device and Method," assigned to the assignee of the subject application, and which is hereby incorporated by reference in its entirety.

SUMMARY OF THE INVENTION

This invention is directed to a biopsy device that provides ready access to a targeted tissue site within a patient's body and provides for the separation and capture of a tissue specimen from the target tissue site. More specifically, the biopsy device provides for a split tissue specimen which greatly facilitates a accurate pathological examination upon its removal from the patient's body.

The biopsy device of the invention generally includes an elongated probe having a proximal end and a distal end and an inner lumen extending therein. A distal probe section is provided which has transverse dimensions less than adjacent portions of the probe and which has one and preferably a plurality of apertures in a wall thereof in fluid communication with the probe's inner lumen. A circular electrode or a pair of opposed semicircular electrodes are slidably disposed about the probe member and are configured for longitudinal translation along a length and preferably the entire length of the small dimensioned distal probe section. The electrode or electrodes are disposed in a plane or planes which are perpendicular and transverse to the longitudinal axis of the probe.

The proximal end of the probe is configured to allow the inner lumen of the probe to be connected to a vacuum source, so that when a vacuum is applied to the inner lumen, tissue adjacent to the small dimensioned distal probe section is pulled into contact with the distal probe section through action of the vacuum through the apertures thereof and thereby fix the tissue specimen to the distal probe section. With the tissue of the specimen secured to the distal probe section, the circular or semicircular electrodes powered by high frequency (RF) electrical power may then be advanced distally to thereby separate the tissue specimen from the tissue bed to which the tissue is secured and supported. The probe and the tissue specimen secured thereto may then be withdrawn from the patient.

In present embodiment of the invention, the biopsy device has a thin, arcuate shaped distal electrode connected to the distal end of the probe and spaced distally therefrom as disclosed in copending applications Ser. No. 09/477,255, filed on Jan. 4, 2000 and Ser. No. 09/057,303 filed on Apr. 8, 1998, which are hereby incorporated herein in their entirety. The distal arcuate electrode lies in a plane that is parallel to and generally passes through a longitudinal axis of the elongated probe. The cordal dimension of the distal electrode is at least the same dimension as the diameter of the distal end of the elongated probe, preferably greater than the diameter of the distal end to ensure that an opening is made through the tissue to the target site and through the suspicious tissue by the electrode which is large enough to allow the biopsy device to be readily advanced. Moreover, because the distal electrode passes through the desired tissue for the specimen, it makes a planar cut through the desired specimen, so that when the circular or semicircular electrodes are advanced over the small dimensioned distal probe section to cut the specimen from the supporting tissue, the specimen is split or is separated into two half specimens.

In a presently preferred embodiment the biopsy device is provided with an outer sheath that is slidably disposed along a length of the probe so as to cover the small dimensioned distal probe section during advancement through tissue and to open and allow specimen tissue to be pulled into contact with the small dimensioned distal probe section when a vacuum is applied to the inner lumen of the probe and the tissue of the specimen is severed from the adjacent supporting tissue by the longitudinal translation of the RF powered circular or semicircular electrodes. The electrodes may be secured to the distal end of the sheath so that the specimen(s) can be separated from the adjacent tissue while the sheath closes over the small dimensioned distal probe section thereby capturing the severed specimen(s) within the interior

of the sheath. The biopsy device may then withdrawn from the patient, and once withdrawn, the specimen or specimen halves secured to the distal probe section maybe removed for subsequent pathological examination.

The distal electrode is connected by means of an electrical conductor which extends to the proximal extremity of the probe, preferably through the inner lumen of the probe to a high frequency, e.g. RF, electrical power. The proximal circular electrode or semicircular electrodes may have their own supporting structure or may be supported as described above from the distal end of the outer sheath. An elongated electrical conductor connects the proximal circular electrode or a pair of elongated electrical conductors connects the proximal electrode to a high frequency, e.g. RF, electrical power which may be the same power source which powers the distal electrode or a separate power source. When the proximal circular electrode or semicircular electrodes are secured to the distal end of the outer sheath, the conductor(s) which connects the proximal electrode(s) may extend through the wall of the outer sheath. The high frequency power for the proximal electrode or electrodes is usually greater than the high frequency power required by the distal electrode. However, generally the proximal electrode(s) are operated at a different time in the procedure so a single power source can be readily programmed to operate at the different electrical power levels required by the electrodes of the present device.

The probe, the proximal electrode and the outer sheath are preferably configured as a disposable unit which may be hand operated or powered by a hand unit connected to a suitable controller.

These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a removable biopsy device having features of the invention seated within a handle with the outer sheath of the device in an opened configuration.

FIG. **2** is a perspective view of the biopsy device shown in FIG. **1** removed from the handle.

FIG. **3** is a perspective view of the biopsy device shown in FIG. **2** rotated 180° about its longitudinal axis.

FIG. **4** is an enlarged perspective view of the distal section of the biopsy device shown in FIG. **2** with the outer sheath in an opened configuration.

FIG. **5** is an enlarged perspective view of the distal section of the biopsy device shown in FIG. **2** with the outer sheath in a closed configuration.

FIG. **6** is a longitudinal cross-sectional view of the device shown in FIG. **2** taken along the lines **6—6**.

FIG. **7** is an enlarged longitudinal cross-sectional view of the distal section of the device shown in FIG. **6**.

FIG. **8** is a transverse cross sectional view of the device shown in FIG. **7** taken along the lines **8—8**.

FIG. **9** is a transverse cross sectional view of the device shown in FIG. **7** taken along the lines **9—9**.

FIG. **10** is a transverse cross sectional view of the device shown in FIG. **7** taken along the lines **10—10**.

FIG. **11** is an enlarged longitudinal cross-sectional view of the distal section of the device shown in FIG. **6** rotated 90° from the view shown in FIG. **7**.

FIG. **12** is an enlarged longitudinal cross-sectional view of the distal section of the device as shown in FIG. **11** with the outer sheath in a closed configuration.

FIG. **13** is a transverse cross sectional view of the device shown in FIG. **1 1** taken along the lines **13—13**.

FIG. **14** is a transverse cross sectional view of the device shown in FIG. **12** taken along the lines **14—14**.

FIG. **15** schematically illustrates an operative system embodying the devices of the invention.

FIG. **16** is a transverse cross sectional view of the device shown in FIG. **12** disposed with a tissue site and tissue at the site held against the surface of the distal extremity by the action of a vacuum within the inner lumen of the probe.

FIG. **17** is a transverse cross sectional view of the device shown in FIG. **15** with the first electrode and outer sheath in a closed configuration with a separated tissue specimen within the space. between the distal extremity **20** and the interior of the outer sheath **14**.

FIG. **18** is a perspective view of an alternative probe member for the biopsy device.

FIG. **19** is a transverse cross-sectional view of the biopsy device shown in FIG. **18** taken along the lines **19—19**.

DETAILED DESCRIPTION OF THE INVENTION

Reference is made to FIGS. **1–14** which illustrate a biopsy device **10** embodying features of the invention. The device **10** generally includes an elongated probe member **11**, a first tissue cutting electrode **12**, a second tissue cutting electrode **13** and an outer sheath **14** slidably disposed about the probe **11**. In one embodiment of the invention shown in FIG. **1**, the device **10** is a disposable device and is configured to be mounted on a handle **15** which provides electrical power and control to the device.

The probe member **11** has a proximal section **16** configured for slidable disposition within the inner lumen **17** of the outer sheath **14** and a distal section **18** which includes a distal extremity **20** which is configured to secure tissue from a tissue site which is to form the specimen and an enlarged distal end **21** to which the second electrode **13** is secured.

As shown in more detail in FIGS. **6–10**, the probe member **11** is provided with an inner lumen **22** which extends from the distal extremity **20** to a connection member **23** on the proximal end **24** of the probe member **11** and which is in fluid communication with the plurality of aspiration ports **25** provided on the distal extremity **20** of the probe member **11**. The proximal end **24** of the probe member **11** and the connection member **23** are secured within the housing **26** as best shown in FIG. **6**.

The outer sheath **14** is slidably disposed about the proximal section of the probe member **11** and has a proximal end secured to a slidable collar **27** within the housing **26**. The collar **27** is provided with an arm **28** which is configured to seat within a receiving opening on a driver (not shown) provided in the handle **15**. The collar **27** is configured to be slidably disposed within the housing so that the driver on the handle can move the arm **28** and as a result translate the outer tubular sheath as shown by the arrow **30** in FIG. **6** between an opened and closed (shown in phantom) configuration.

The housing **26** is provided with distal projection **31** and proximal projection **32** which are designed to tightly seat within receiving openings (not shown) provided in the handle to effect a snap fit of the housing **26** within a recess **33** provided in the upper surface **34** of handle as shown in FIG. **1**. A second long recess **35** is provided in the upper surface **34** of handle **15** which is contiguous with recess **33** and which is configured to receive the connection member

23 tightly enough to prevent accidental excursions out of the recess. As shown in FIG. 6, the connection member 23 has an inner lumen 36 in fluid communication with the inner lumen 22 of the probe member 11.

The first electrode 12, which is circular and disposed about the probe member 11, is connected to electrical conductors and support elements 37 and 38 which extend through the wall of outer sheath 14. This construction allows the first electrode to travel longitudinally with the outer sheath over the distal extremity 20 of the probe member 11 and in this manner cut the tissue specimen held against the distal extremity by the action of a vacuum within the inner lumen 22 from the tissue site and at the same time cover the separated tissue specimen with the outer sheath so that the specimen can be removed with device 10 from the patient with the same movement.

As shown in FIG. 6, the proximal end(s) of the electrical conductors 37 and 38 are secured to the conducting tubular element 40 provided in the arm 28 of collar 27 which drives and withdraws the outer sheath 14.

The second electrode 13 has an arcuate portion which is spaced distally away from the distal end 21 and has a maximum chord (i.e. distance between the ends of the arcuate portion) which is preferably larger than the maximum diameter of the distal end. The maximum width of the second electrode 13 is preferably about 20 to about 50% greater than the maximum outside transverse dimension of the distal end 21 of the probe 11. The second electrode 13 can be spaced distally from an outer surface of the distal end 21 by a distance of about 0.01 to about 0.05 inch, preferably about 0.02 to about 0.04 inch. As best shown in FIGS. 6 and 7, the arcuate second electrode 13 is formed out of the distal extremity of electrical conductor 41. The proximal end 42 of the conductor 41 is electrically connected to tubular conductor 43 provided in the proximal projection 32 of housing 26 as shown in FIG. 6.

The shaft of the device 10 which extends out from the housing 26 may have a length of about 3 to about 15 cm, preferably, about 5 to about 13 cm, and more specifically, about 8 to about 9 cm for breast biopsy use. To assist in properly locating the shaft of device 10 during advancement thereof into a patient's body, (as described below), the distal extremity 20 of the probe and the outer sheath 14 may be provided with markers at desirable locations that provide enhanced visualization by ultrasound or X-ray. For ultrasonic location an echogenic polymer coating that increases contrast resolution in ultrasound imaging devices such as ECHOCOAT™ by STS Biopolymers, of Henrietta, N.Y. In addition, the surfaces of the device in contact with tissue may be provided with a suitable lubricious coating such as a hydrophilic material or a flouropolymer.

The proximal portion of the probe 11 generally has an outer dimension of about 3 to about 10 mm and a inside dimension of about 2 to about 6 mm and it may be desirable in some embodiments to have a close fit between the proximal section of the probe 11 and the inner lumen 17 of outer sheath 14 to avoid a gap there between which can catch or snag on adjacent tissue during advancement through tissue and impede advancement.

The first and second electrodes 12 and 13 can be generally conductive wire formed of metallic materials such as stainless steel. The shaft components from which the probe 11 and outer sheath 14 are formed may be conventional medical grade polymer materials such as polycarbonate and liquid crystal polymer (LCP), respectively.

The biopsy device 10 may be use to obtain a tissue specimen utilizing the operation system 50 schematically shown in FIG. 15. The operating system 50 generally includes a high frequency (e.g. RF) electrical power generator 51, which is electrically connected to both the first and second tissue cutting electrodes 12 and 13 on the biopsy device 10 through conductors 52 and 53. The power output and the receiving element is controlled by the controller 54. The RF generator 51 is electrically connected to the controller through conductors 55 and 56 and preferably operates at about 300 to about 1000 KHz, specifically, about 700 to about 900 KHz and has a power output of about 50 to about 150 watts, preferably, about 80 to about 100 watts. Vacuum is generated by the vacuum pump 57 which is connected in a fluid flow relationship with the inner lumen (not shown) provided in conduit 58 which leads to a vacuum trap 59. Vacuum is applied to the inner lumen 22 of the probe member 11 through inner lumen 36 of connection member 23 connected to the vacuum trap. A meter actuation and control cable 60 is provided to power and control the actuation elements in handle 15.

A tissue specimen is obtained with the device 10 by pressing the second electrode 13 of the device 10 against an exterior site on the patient's skin proximate to the tissue site where the specimen is to be obtained. High frequency electrical power from the generator 51 passes through the electrical conductor 41 to energize the second electrode 13 and the device 10 with the second electrode energized is advanced through the tissue until the distal end 21 of the device has passed through the tissue which is to form the specimen. The action of the energized second electrode 13 forms a planar cut through the desired tissue bed and allows the probe to readily pass through the tissue. Very little collateral tissue damage is done by the accessing second electrode 13 at the margins where the tissue cut is made. It should be noted that many physicians may prefer to first make an incision with a scalpel through the patient's skin and expose subcutaneous tissue before passing the device 10 through the tissue on the belief that the cutting action of a high frequency powered electrode such as second electrode 13 can cause excessive scar tissue formation on the access site. The device is preferably advanced through the patient's tissue to the specimen site with the outer sheath 14 in a closed configuration. Once the device 10 is in the desired location, the outer sheath 14 can be withdrawn to an opened configuration to expose the distal extremity 20 of the probe 11 by action of the driver (not shown) operatively connected to the arm 28 of collar 27. With the distal extremity 20 of the probe 11 exposed, a vacuum can be generated within the inner lumen 22 of probe 11 by the action of vacuum pump 57. The vacuum generated in the inner lumen 22, acting through the ports 25 in the distal extremity 20 draws tissue at the site against the surface of the distal extremity and holds the tissue against the surface as shown in FIG. 16. The first electrode 12 may then be energized by high frequency electrical power and then driven distally along with the outer sheath 14 to which the electrode 12 is secured to sever a generally cylindrical shaped tissue specimen 61 from the adjacent tissue site and cover the severed tissue specimen with the sheath 14 as shown in FIG. 17. The biopsy device may then be removed from the patient. Due to the planar cut made by the second electrode 13 through the tissue from which the specimen is to be obtained, the cylindrical specimen 61 is a split specimen which greatly aids in its evaluation. It may be desirable to provide an accessing cannula on the exterior of the outer sheath 14 which can be left in the patient with its distal end at the site from which the specimen was obtained to allow a marker or other device to be deposited at the site in case further procedures or treatments

are necessary or desirable and the site has to be located at a later time. After the biopsy procedure is completed, the incision formed by the initial cut through the patient's skin appropriately closed.

An alternative probe member **70** embodying features of the invention is depicted in FIGS. **18** and **19**. In this alternative the distal extremity **71** of the probe device **70** is of tubular construction as shown. The tissue cutting electrode **72** on the distal end of the probe member **70** has an expandable construction which is disclosed in copending application Ser. No. 09/477,255, filed Jan. 4, 2000, entitle Apparatus and Method for Accessing A Biopsy Site, by Burbank et al., which is incorporated herein by reference in its entirety. The tubular distal extremity **71** has a plurality of ports **73** which are in fluid communication with an inner lumen **75**. Cutting electrode **72** is secured to the enlarged distal end **74**. An electrical conductor **76** (shown in FIG. **19**) extends through inner lumen **75** and is electrically connected to electrode **72**. An outer sheath **77** extends about the probe member **70**. The probe **70** is used in the same manner described above with an outer sheath and circular tissue cutting electrode for the embodiment shown in FIGS. **1–14**. The outer sheath may be configured to allow the probe **70** to be withdrawn with the specimen for specimen removal leaving the distal end of the sheath located at the biopsy site, thus eliminating the need for an accessing cannula.

Those skilled in the art will recognize that various modifications may be made to the specific embodiments illustrated above. In addition, it will be readily appreciated that other types of instruments may be inserted into the tissue site through the outer sheath or a suitable cannula in addition to or in place of the instruments described above. These and other modifications that may suggest themselves are considered to be within the scope of the claims that follow.

What is claimed is:

1. An elongated device for separation of a tissue specimen from a target tissue site, comprising:

a. an elongated probe which has a proximal end, a distal end, a longitudinal axis, an inner lumen extending within the probe and which has a distal extremity with at least one aperture in a wall thereof that is in fluid communication with the inner lumen extending within the probe and with a transverse dimension substantially less than portions of the probe distal to the distal extremity; and

b. a first tissue cutting electrode which is at least partially disposed about the elongated probe, which lies in a plane transverse to the longitudinal axis of the probe, which has an inner dimension substantially greater that the small transverse dimension of the distal extremity of the probe, which is configured for longitudinal movement along a length of the distal extremity of the probe and which is configured to be electrically connected to a high frequency power source.

2. The elongated device of claim **1** including a fluid connection on the proximal end of the elongated probe which is in fluid communication with the inner lumen extending within the probe and which is configured for fluid communication with a vacuum source.

3. The elongated device of claim **1** wherein the first electrode is electrically connected to the power source by a first elongated electrical conductor having a distal end electrically connected to the first electrode and a proximal end configured for electrical connection to a source of high frequency electrical power source.

4. The elongated device of claim **1** including a second tissue cutting electrode spaced distal to the distal end of the elongated inner probe to facilitate advancement of the probe through tissue to the target site.

5. The elongated device of claim **4** including a second elongated electrical conductor having a distal end electrically connected to the second electrode and a proximal end configured for electrical connection to a high frequency electrical power source.

6. The elongated device of claim **4** wherein the second electrode has an arcuate shape and has a chord length at least as great as the transverse dimension of the probe distal to the distal extremity.

7. The elongated device of claim **4** wherein the second electrode lies in a plane which is parallel to the longitudinal axis of the probe.

8. The elongated device of claim **2** wherein the distal extremity has a plurality of apertures which are in fluid communication with the inner lumen.

9. The elongated device of claim **8** wherein the distal extremity of the probe has a circular transverse cross sectional shape.

10. The elongated device of claim **1** including an outer sheath which as proximal and distal ends, which has an inner lumen extending therein, which is slidably disposed about the elongated probe member and which is configured to be advanced over the distal extremity and thereby capture any tissue separated by the first electrode.

11. The elongated device of claim **10** wherein the first electrode is secured to the distal end of the outer sheath.

12. The elongated device of claim **11** including a first electrical conductor having a distal end electrically connected to the first electrode and a proximal end configured to be electrically connected to an electrical power source.

13. The elongated device of claim **12** wherein the first electrical conductor extends longitudinally through a wall of the outer sheath.

14. An elongated tissue biopsy device, comprising:

a. an elongated probe which has a proximal end and a distal end, which has a longitudinal axis, which has an inner lumen extending within a portion of the probe and which has a distal extremity with at least one transverse dimension less than an adjacent portion of the probe distal to the distal extremity and with at least one aperture that is in fluid communication with the inner lumen extending within the probe;

b. a proximal electrode which is at least partially disposed about the elongated probe, which lies in a plane that is transverse to the longitudinal axis and which is configured for longitudinal movement along a length of the small dimensioned distal probe section;

c. a first elongated electrical conductor having a distal end electrically connected to the first electrode and a proximal end configured for electrical connection to a high frequency electrical power source;

d. an arcuate second tissue cutting electrode which is spaced distal to the distal end of the probe, which has a chordal length at least as great as the largest transverse dimension of the distal end of the probe and which lies in a plane parallel to the longitudinal axis of the probe; and

e. a second elongated electrical conductor having a distal end electrically connected to the second electrode and a proximal end configured for electrical connection to a high frequency electrical power source.

15. An elongated biopsy device, comprising:

a. an elongated outer tubular member which has proximal and distal ends, a first port in the distal end, a second

port in the proximal end and an inner lumen extending therein from the first port in the distal end to the second port in the proximal end;

b. a circular first electrode secured to the distal end of the outer tubular member;

c. an elongated first electrical conductor which has a distal end electrically connected to the circular first electrode and a proximal end configured for electrical connection to a high frequency electrical power source;

d. an elongated probe which is slidably disposed within the inner lumen of the outer tubular member, which has an inner lumen extending therein, having a distal extremity with at least one aperture that is in fluid communication with the inner lumen extending within the interior of the probe;

e. an arcuate second electrode which is spaced distally of the distal end of the elongated inner probe; and

f. an elongated second electrical conductor which has a distal end electrically connected to the arcuate electrode and a proximal end configured for electrical connection to a high frequency electrical power source.

16. The biopsy device of claim **15** wherein the first elongated conductor extends through a wall of the outer tubular member.

17. The biopsy device of claim **16** wherein the second electrode has an expanded deployed configuration with a width greater than an outside transverse dimension of the distal end of the probe and a contracted configuration with a width that is equal to or less than an inside transverse dimension of the inner lumen of the outer tubular member.

18. A method of separating a specimen of tissue at a desired site within a patient's body, comprising:

a. providing an elongated biopsy device of claim **15**;

b. energizing the second electrode while advancing the elongated biopsy device into the patient's body until the distal end of the device has been advanced at least partially into tissue at a desired site within the patient's body;

c. withdrawing the outer tubular member to expose the distal extremity of the probe;

d. applying a vacuum to the inner lumen of the probe to secure tissue to the distal extremity;

e. energizing the first electrode While distally advancing the first electrode over the distal extremity of the probe to separate a tissue specimen from the tissue site;

f. advancing the outer tubular member over the separated tissue specimen; and

g. withdrawing the elongated device with the tissue specimen from the patient.

19. A method of obtaining a plurality of tissue specimens at a desired site within a patient's body, comprising:

a. providing an elongated biopsy device of claim **15** wherein the outer tubular member is configured to allow the probe member to be withdrawn therethrough;

b. energizing the second electrode while advancing the elongated biopsy device in the patient's body until the distal end of the device has been advanced at least partially into tissue at a desired site within the patient's body;

c. withdrawing the outer tubular member to expose the distal extremity of the probe;

d. applying a vacuum to the inner lumen of the probe to secure tissue to the distal extremity;

e. energizing the first electrode while distally advancing the first electrode over the distal extremity of the probe to separate a tissue specimen from the tissue site;

f. withdrawing the elongated probe member with the tissue specimen attached thereto from the patient leaving the outer tubular member in place with the distal end thereof at the tissue site;

g. advancing an elongated probe member as described in claim **15** through the outer tubular member to the tissue site and adjusting the relative positions of the probe and outer tubular member so as to expose the distal extremity of the probe member;

h. repeating steps d. and e. to obtain another tissue specimen; and

i. after step h., withdrawing the probe member and specimen from the patient.

* * * * *